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Mary J. Davis

University of Kentucky College of Law, mjdavis@uky.edu

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THE BATTLE OVER IMPLIED PREEMPTION: PRODUCTS LIABILITY AND THE FDA

MARY J. DAVIS*

Abstract: A mere five years ago, the Food and Drug Administration (the "FDA") began, for the first time in its 100-year history, to take the position that its prescription drug labeling regulations defeated the ability of injured plaintiffs to pursue common law tort claims based on the adequacy of the labeling. This position, radical to many and rational to others, places federal preemption of prescription drug labeling actions directly in the center of the debate over the proper roles of federal regulation and state tort laws in promoting product safety. The U.S. Supreme Court has contributed to this debate with several product liability preemption decisions in the past two decades. Seeking to promote both understanding and balance regarding the operation of preemption doctrine within products liability, this Article provides a comprehensive explanation of the applicability of preemption doctrine to prescription drug product liability actions. It explores the history of preemption doctrine as it relates to the food and drug laws, evaluates the arguments posited in favor of and against preemption, assesses the FDA's position on the application of that doctrine to current litigation, and provides direction to courts in defining the boundaries of implied preemption.

INTRODUCTION

Federal preemption of common law tort actions has become the subject of conspiracy theorists, dedicated tort reformers, and all those in between.¹ Described on the one hand as a massive effort at the fed-

* Stites & Harbison Professor of Law, University of Kentucky College of Law. B.A. University of Virginia, 1979; J.D. Wake Forest University School of Law, 1985. I would like to thank the participants at the Randall-Park Colloquium Speakers Series, University of Kentucky College of Law, for their observations on an earlier draft. Thanks also to Professors Richard Ausness, David Owen, and Joe Page for their helpful insights, and to Tammy Howard, University of Kentucky College of Law, Class of 2006, for her fine research assistance.

¹ See Ralph Lindeman, *Agencies Move to Override State Law as Part of Federal Rulemaking Process*, 34 BNA PRODUCT SAFETY & LIAB. REP. 364, 364 (2006); MARGARET H. CLUNE, CTR. FOR PROGRESSIVE REFORM, *STEALTH TORT REFORM: HOW THE BUSH ADMINISTRATION'S*

eral level to chip away at state tort law,² and on the other as a good thing, preferable to standards set by state juries,³ advocates on both sides of the preemption debate have an opinion about whether federal regulations should defeat state common law tort actions.⁴ The U.S. Supreme Court has addressed preemption of product liability claims on several occasions since its 1992 decision in *Cipollone v. Liggett Group, Inc.*,⁵ which put federal preemption of product liability actions in the forefront of the debate over the role of federal regulation in effecting product safety.⁶ The political dimension of this debate continues, especially in the area of preemption of prescription drug product liability claims.⁷

A mere five years ago, the Food and Drug Administration (the "FDA")⁸ for the first time in its 100-year history asserted that its prescription drug labeling regulations preempted injured plaintiffs' common law tort claims based on the adequacy of the labeling.⁹ Common law products liability doctrines typically do not treat federally approved prescription drug labeling as conclusive on the question of the label's adequacy.¹⁰ The classic reasoning underlying this con-

AGGRESSIVE USE OF THE PREEMPTION DOCTRINE HURTS CONSUMERS 1-2, 7-9 (2004), <http://www.progressiveregulation.org/articles/preemption.pdf>.

² Lindeman, *supra* note 1, at 364 (quoting Susan Frederick, Senior Director with the National Conference of State Legislatures); *id.* (federal agency statements favoring preemption are a "sneak attack on consumer rights"); *see also* CLUNE, *supra* note 1, at 1 (describing new FDA position on preemption as "anti-consumer tort reform agenda").

³ Lindeman, *supra* note 1, at 364 (quoting David Price, Senior Counsel with the Washington Legal Foundation, a conservative legal reform group).

⁴ For a discussion of the general debate on preemption by agency action, *see generally* Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007), and Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353 (2006).

⁵ 505 U.S. 504, 518-19 (1992) (involving express preemption of product liability actions by federal cigarette labeling laws).

⁶ *See* *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 443-54 (2005); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62-70 (2002); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-53 (2000); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 867-86 (1999); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484-91 (1996).

⁷ Compare CLUNE, *supra* note 1, at 1 (describing new FDA position on preemption as "anti-consumer tort reform agenda"), with News Release, Wash. Legal Found., WLF Hails FDA Policy Statement on Preemption of Failure-to-Warn Suits (Jan. 25, 2006), *available at* <http://www.wlf.org/upload/012506RS.pdf> (lauding the position, having "call[ed] on FDA to issue such a policy statement for several years").

⁸ 21 U.S.C. § 393 (2000) (authorizing the creation of the Food and Drug Administration as the agency responsible for administering the Food, Drug, and Cosmetic Act).

⁹ *See* Mary Ellen Egan, *Tort Turf*, FORBES, Apr. 26, 2004, at 48.

¹⁰ RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL HARM § 16 cmts. b, e (Proposed Final Draft Mar 17, 2005) (noting that the lawmaking process is "insufficiently atten-

clusion is that governmental regulations are based on narrowly defined goals, supported by limited information provided substantially by the regulated entity, and typically do not include setting optimal standards of care for all circumstances; rather, they set minimum standards not intended to prevent the operation of other remedial mechanisms such as common law tort claims.¹¹ Consequently, more exacting state tort law standards of care do not conflict, but operate concurrently with the federal requirements.¹²

tive" to interests of injured and that an "unusual situation" arises when governmental compliance is treated as conclusive of due care); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 4(b) (1998); RESTATEMENT (SECOND) OF TORTS § 288C (1965). *See generally* DAN B. DOBBS, *THE LAW OF TORTS* § 224 (2000); DAVID G. OWEN, *PRODUCTS LIABILITY LAW* § 14.3, at 888 (2005) [hereinafter OWEN, *PRODUCTS LIABILITY*]; *see also* DAVID G. OWEN, M. STUART MADDEN & MARY J. DAVIS, *MADDEN AND OWEN ON PRODUCTS LIABILITY* § 16:3, at 134 (3d ed. 2000) [hereinafter MADDEN AND OWEN *ON PRODUCTS LIABILITY*].

For a discussion of the doctrine as applied to products liability actions, *see generally* Richard C. Ausness, *The Case for a "Strong" Regulatory Compliance Defense*, 55 MD. L. REV. 1210 (1996); Teresa Moran Schwartz, *Regulatory Standards and Products Liability: Striking the Right Balance Between the Two*, 30 U. MICH. J.L. REFORM 431 (1997); Teresa Moran Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121 (1988); and Symposium, *Regulatory Compliance as a Defense to Products Liability*, 88 GEO. L.J. 2049 (2000).

On the subject of regulatory compliance regarding prescription drugs, *see generally* David R. Geiger & Mark D. Rosen, *Rationalizing Product Liability for Prescription Drugs: Implied Preemption, Federal Common Law, and Other Paths to Uniform Pharmaceutical Safety Standards*, 45 DEPAUL L. REV. 395 (1996) (advocating a regulatory compliance defense for pharmaceuticals); and Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 335 (1985) ("Regulatory agencies are equipped to make the risk comparisons on which all progressive transformation of the risk environment must be based. The courts are simply not qualified to second-guess such decisions; when they choose to do so they routinely make regressive risk choices.").

¹¹ *See* DOBBS, *supra* note 10, § 224, at 573. Dan Dobbs notes:

When it comes to technological standards, they are quickly outdated with no guarantee that the legislature or regulators will have time or information necessary to update them. Beyond that, many statutes are written in response to lobbying efforts of the industry they purport to regulate, and they are not likely to represent a balanced attempt by neutral parties to achieve appropriate safety.

Id. Some states statutorily provide a regulatory compliance defense. *See, e.g.*, COLO. REV. STAT. § 13-21-403(1) (2005) (regulatory compliance presumes due care); IND. CODE § 34-20-5-1 (1998) (same); MICH. COMP. LAWS ANN. § 600.2946(5) (West 1995) (immunity on drug manufacturers based on federal regulatory compliance). *See generally* OWEN, *PRODUCTS LIABILITY*, *supra* note 10, § 14.3, at 894 ("About a dozen states have enacted products liability reform statutes concerning the effect of a manufacturer's compliance with a governmental safety standard.").

¹² *Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989); *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986); *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 730

When state laws, including tort claims, do conflict with federal regulation, they are preempted under authority of the Supremacy Clause of the U.S. Constitution.¹³ The key to establishing preemption is a finding of congressional intent to preempt, called “the ultimate touchstone” of preemption analysis.¹⁴ Congress may evidence this intent by including in a law an express preemption provision, which must be analyzed to determine the extent of that intent.¹⁵ When Congress does not include such a provision, implied preemption doctrines operate.¹⁶ The Federal Food, Drug, and Cosmetic Act (the “FDCA”)¹⁷ does not contain a generally applicable express preemption provision.¹⁸ Consequently, implied preemption doctrines apply.¹⁹

The FDA’s recent position favoring preemption—that its labeling regulations establish optimal standards in some cases from which state law may not deviate²⁰—places federal preemption of prescription

(D. Minn. 2005); *Merrell Dow Pharm., Inc. v. Oxendine*, 649 A.2d 825, 828 (D.C. 1994); see also MADDEN AND OWEN ON PRODUCTS LIABILITY, *supra* note 10, § 28:6, at 909–13.

¹³ U.S. CONST. art. VI, cl. 2 (“The Constitution, and laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . .”). On the application of preemption to tort laws, see generally Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085 (2000); Betsy J. Grey, *The New Federalism Jurisprudence and National Tort Reform*, 59 WASH. & LEE L. REV. 475, 503–10 (2002); Alexander K. Haas, *Chipping Away at State Tort Remedies Through Preemption Jurisprudence: Geier v. American Honda Motor Co.*, 89 CAL. L. REV. 1927 (2001); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 290–91 (2000); and Symposium, *Federal Preemption of State Tort Law: The Problem of Medical Drugs and Devices*, 33 PEPP. L. REV. 1 (2005).

¹⁴ *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978).

¹⁵ *Cipollone*, 505 U.S. at 516. See generally Mary J. Davis, *Unmasking the Presumption Against Preemption*, 53 S.C. L. REV. 967 (2002) (explaining history of preemption doctrine).

¹⁶ See, e.g., *Geier*, 529 U.S. at 867–68 (express preemption provision not exclusive in determining scope of preemption; implied preemption of claims based on failure to include driver’s side air bags).

¹⁷ 21 U.S.C.A §§ 301–397 (West 1999 & Supp. 2007).

¹⁸ See *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1035 (S.D. Ill. 2001) (explaining that portion of FDCA dealing with pharmaceuticals does not contain preemption provision); *McCallister v. Purdue Pharma L.P.*, 164 F. Supp. 2d 783, 792 (S.D. W. Va. 2001) (same); *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972, at *2 (S.D. Ind. Jan. 28, 2002) (same); see also *Geiger & Rosen*, *supra* note 10, at 400 (noting there is no express preemption provision in prescription drug labeling sections of FDCA); James T. O’Reilly, *A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?*, 58 FOOD & DRUG L.J. 287, 290 (2003) (same).

¹⁹ See *Geiger & Rosen*, *supra* note 10, at 400.

²⁰ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–36 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601). The prescription drug labeling regulation became final and effective on June 30, 2006. *Id.* at 3928. The regulation is discussed in detail in Part III, *infra* notes 149–348.

drug labeling actions directly in the center of the debate over the proper role of federal regulation in effecting product safety.²¹ Seeking to promote both an understanding of and a balance in the operation of preemption doctrine within products liability, this Article provides a comprehensive explanation of the applicability of preemption doctrine to prescription drug product liability actions.²² The Article explores the relevance of the FDA's changed position on that doctrine and provides direction to courts charged with defining the boundaries of implied preemption in this critical area.²³

Part I presents background on the recent cases that raise the preemption issue.²⁴ Part II examines in greater detail the regulatory scheme under the FDCA, placing the preemption issue in context.²⁵ Part III explores the evolution of implied preemption doctrine generally and then applies that understanding to food and drug regulation.²⁶ Part IV analyzes critically the basis for implied conflict preemption under the FDCA and evaluates those arguments in a manner consistent with a deeper understanding of the Supreme Court's preemption jurisprudence.²⁷ In doing so, Part IV addresses the effect the FDA's recent change in position has on implied preemption analysis.²⁸

The proper weight of an agency's determination of preemptive scope has generated much debate within the Supreme Court²⁹ and among commentators.³⁰ The Court has not answered the question of how an agency position affects the operation of implied conflict pre-

²¹ For two recent articles on this debate, see generally Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT L., art. 5 (2006); and Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L., art. 4 (2006).

²² See *infra* notes 32–469 and accompanying text.

²³ See *infra* notes 32–469 and accompanying text.

²⁴ See *infra* notes 32–61 and accompanying text.

²⁵ See *infra* notes 62–148 and accompanying text.

²⁶ See *infra* notes 149–348 and accompanying text.

²⁷ See *infra* notes 349–457 and accompanying text.

²⁸ See *infra* notes 349–457 and accompanying text.

²⁹ See, e.g., *Medtronic*, 518 U.S. at 474–514 (Justices Stevens, Breyer, and O'Connor disagreed about level of deference to FDA's preemption position regarding medical device regulations).

³⁰ See, e.g., Richard C. Ausness, "After You, My Dear Alphonse!": Should the Courts Defer to the FDA's New Interpretation of § 360k(a) of the Medical Device Amendments?, 80 TUL. L. REV. 727, 767–75 (2006); Allison M. Zieve & Brian Wolfman, *The FDA's Argument for Eradicating State Tort Law: Why It Is Wrong and Warrants No Deference*, 34 BNA PRODUCT SAFETY & LIAB. REP. 308, 308 (2006). See generally Paul E. McGreal, *Some Rice with Your Chevron?: Presumption and Deference in Regulatory Preemption*, 45 CASE W. RES. L. REV. 823 (1995); Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737 (2004).

emption doctrine, nor has it addressed how the historic primacy of state regulation in the area of health and safety is to be considered in the balance. Part IV evaluates the Court's modern preemption jurisprudence and concludes that it does not support implied conflict preemption of prescription drug labeling products liability actions.³¹ An agency attempting to alter the long-standing, historic balance between federal safety regulation and common law tort principles and to establish actual conflict with underlying tort principles must justify its position with something more than evolving notions of valid scientific inquiry and shifting political positions. Traditional tort law continues to play an important role in providing compensation for injured consumers, and the Supreme Court's preemption doctrine requires much more than an agency's change of heart to alter that conclusion. The boundary between state tort law and federal regulation of prescription drug labeling continues to be well-marked, preserving the traditional place for the operation of state tort law.

I. SETTING THE STAGE FOR PREEMPTION

Before 2002, the FDA maintained the position that its product approval process and state tort liability usually operate independently—each providing a significant, yet distinct, layer of consumer protection.³² In 2002, the FDA announced a significant shift in its position,

³¹ See *infra* notes 349–457 and accompanying text.

³² Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 57 FOOD & DRUG L.J. 7, 11 (1997) (Ms. Porter was FDA Chief Counsel at the time of the article's publication); see also Foreign Rule, 63 Fed. Reg. 66378, 66384 (Nov. 28, 2003) (to be codified at 48 C.F.R. pt. 5125) ("FDA's regulations establish the minimal standards necessary, but were not intended to preclude the States from imposing additional labeling requirements."). See generally O'Reilly, *supra* note 18, at 288 ("Until DHHS [Department of Health & Human Services] asserted prescription drug preemption in [*Motus v. Pfizer, Inc.*], FDA had remained aloof from preemption arguments that often had been made by prescription drug manufacturers in defense of individual products liability lawsuits."). A few months before the *Motus* brief, the FDA took a similar preemption position in another products liability action which was ultimately decided on other grounds. See *Bernhardt v. Pfizer, Inc.*, 00 Civ. 4042 (LMM), 00 Civ. 4379 (LMM), 2002 U.S. Dist. LEXIS 16963, at *9–10 (S.D.N.Y. Nov. 16, 2002).

At the time of the United States's *Motus* Amicus Brief, the FDA's General Counsel and architect of the changed preemption position, Daniel Troy, had formerly represented Pfizer, Inc. during his time in private practice. Gary Young, *FDA Strategy Would Preempt Tort Suits: Does It Close Off Vital Drug Data?*, 26 NAT'L L.J., Mar. 1, 2004, at 1. Troy has been criticized for not disclosing his Pfizer ties. *House Cuts OC's Funds for Downplaying Troy's Drug Industry Ties*, FDA WK., July 16, 2004, § 29; see also O'Reilly, *supra* note 18, at 287 (discussing FDA change in position regarding preemption); CLUNE, *supra* note 1, at 2–3 (describing FDA change in position under Troy).

one aggressively in favor of preemption, based on concerns over "the growing propensity of bad scientific reasoning to seep into court cases involving FDA-regulated products."³³ Prescription drug manufacturers, with support from the FDA in the form of amicus briefs, began to take the litigation position that approved prescription drug labeling preempts state tort claims.³⁴ Proponents of the continuing vitality of traditional tort doctrine, however, argue that it establishes a duty of care, protecting citizens in circumstances where the federal government is late in acting or where federal standards are insufficient.³⁵ Reasoning that common law tort claims are a critical component of the states' traditional ability to protect the health and safety of their citizens, one court has noted that "[t]he power of states to govern in this field is considerable and undisputed."³⁶

An example of the tension between these two positions is illustrated by *Motus v. Pfizer, Inc.*, a 2004 case before the U.S. Court of Appeals for the Ninth Circuit, in which the FDA first asserted its new preemption position.³⁷ Plaintiff alleged that the warnings on the anti-

³³ Egan, *supra* note 9; see also Lindeman, *supra* note 1, at 365 (quoting one White House Office of Management and Budget spokesman as saying, "State courts and juries often lack the information, expertise, and staff that the federal agencies rely upon in performing their scientific, risk-based calculation").

³⁴ See, e.g., *Perry v. Novartis Pharm. Corp.*, 456 F. Supp. 2d 678, 688 (E.D. Pa. 2006) (denying motion to dismiss on implied preemption of Elidel warning claims); *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 969 (D. Neb. 2006) (denying motion to dismiss on implied preemption grounds in Zolof case); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 555 (E.D. Pa. 2006) (granting motion to dismiss on FDA's implied preemption of plaintiff's warning claims regarding antidepressant Paxil and risk of suicide), *appeal docketed*, No. 06-3107 (3d Cir. June 21, 2006); *Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163, 1174 (W.D. Wash. 2006) (denying summary judgment based on implied preemption in antidepressant fluoxetine case); *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1058 (W.D. Wis. 2006) (no implied preemption in Prilosec warning case); *McNellis v. Pfizer, Inc.*, No. Civ. 05-1286 JBS, 2005 WL 3752269, at *12-13 (D.N.J. Dec. 29, 2005) (no implied preemption in Zolof case); *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005) (denying summary judgment based on preemption argument in Zolof case); *Needleman v. Pfizer, Inc.*, No. Civ.A. 3:03-CV-3074-N, 2004 WL 1773697, at *6 (N.D. Tex., Aug. 6, 2004) (granting summary judgment for manufacturer based on conflict preemption in Zolof case); *Dusek v. Pfizer, Inc.*, No. Civ.A. H-02-3559, 2004 WL 2191804, at *10 (S.D. Tex. Feb. 20, 2004) (same); see also CLUNE, *supra* note 1, at 2-3.

³⁵ Letter from Sen. Steven J. Rauschenberger, President of Nat'l Conference of State Legislatures, to Mike Leavitt, Sec'y of U.S. Dept. of Health & Human Servs. (Jan. 13, 2006) [hereinafter Letter to Mike Leavitt], available at <http://ncsl.org/statedef/FDArule.htm>.

³⁶ *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 86 (2d Cir. 2006) (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 544 (1992) (Blackmun, J., concurring in part and dissenting in part)).

³⁷ See generally 358 F.3d 659 (9th Cir. 2004), *rev'g* 127 F. Supp. 2d 1085 (C.D. Cal. 2000). The FDA's new position was first expressed in an amicus brief submitted to the Ninth Circuit. See generally Brief for United States as Amicus Curiae Supporting Defendant-Appellant, *Motus*,

depressant Zoloft, a selective serotonin reuptake inhibitor ("SSRI"), were inadequate under state product liability laws because they did not emphasize sufficiently the association between use of the drug and an increased risk of suicide.³⁸ Prior to and during the course of approving Zoloft in 1991, the FDA explored the potential associations between the use of SSRIs and suicide.³⁹ Concerns caused the FDA to convene a committee of experts, the Psycho-pharmacological Drugs Advisory Committee (the "PDAC"), to consider the issue.⁴⁰ In 1991, the PDAC unanimously found that there was no credible evidence to support a conclusion that the antidepressant drugs cause the emergence and/or intensification of suicidality and/or other violent behaviors.⁴¹ The FDA subsequently made suggestions to Pfizer regarding warning language it should incorporate in Zoloft labeling and convinced Pfizer to use the proposed text verbatim.⁴²

Pfizer moved for summary judgment before the district court in *Motus* based on implied conflict preemption, arguing that to permit liability based on state tort laws would defeat the objectives of the regulatory scheme because federal regulators had decided, based on the available scientific evidence, that an additional warning was not required.⁴³ The court denied the motion, finding that the federal regulation which permits a manufacturer to alter a warning without prior FDA approval prevented any conflict with state product liability laws.⁴⁴ The trial court was persuaded by the FDA Commissioner's previous statements favoring the role of unilateral manufacturer labeling changes to increase information provided to health care providers and enhance public safety.⁴⁵ In addition, the trial court noted that,

358 F.3d 659 (No. 02-55372), 2002 WL 32303084 [hereinafter *Motus* Amicus Brief of United States].

³⁸ *Motus*, 127 F. Supp. 2d at 1087-90 (discussing regulatory history of Zoloft and other similar antidepressants known as SSRIs).

³⁹ *Id.* at 1090. Suicidality and the use of SSRIs had been studied earlier in connection with the drug Prozac. *Id.*

⁴⁰ *Id.* at 1088, 1090.

⁴¹ *Id.* at 1090. During the PDAC proceedings, the Director of the Division stated a concern that an unintended side effect of modifying the labeling to raise an increased concern over suicidality "might be a reduction in the use of antidepressants in the treatment of depression, and that the result might cause overall injury to the public health." *Id.*

⁴² *Id.* at 1088. Plaintiff contended that Pfizer drafted the ultimately approved labeling language, not the FDA. *Id.* at n.3.

⁴³ *Motus*, 127 F. Supp. 2d at 1093. Pfizer also argued for implied conflict preemption based on the impossibility of being able to comply with both the federal and state requirements. *Id.* at 1092.

⁴⁴ *Id.* at 1094 (referring to 21 C.F.R. § 314.70(c) (2007)).

⁴⁵ *Id.* The FDA Commissioner had stated, in support of the then-current regulation:

although the FDA concluded that no labeling change was required based on its review of the scientific evidence, the FDA never stated that it would be impermissible to include additional warnings.⁴⁶

In support of Pfizer's appeal of the denial of summary judgment, the FDA argued that although FDA regulations permit a drug's manufacturer to alter or strengthen a warning, it is the FDA, not each state court system applying its own standards, that must approve the warning.⁴⁷ The FDA disagreed with the suggestion that, to constitute an actual conflict for preemption purposes, the FDA must reject a proposed warning change formally because all imaginable warnings that could reasonably have been read as describing or alluding to the association with suicidality would have been false or misleading for lack of scientific support and therefore in conflict with federal law.⁴⁸ The FDA concluded that any state common law damages action that resulted in requiring an unapproved warning would have misbranded the drug per se, thereby subjecting the manufacturer to penalties un-

The commissioner also advises that these labeling requirements do not prohibit a manufacturer . . . from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered. The addition to labeling . . . of additional warnings . . . is not prohibited by these regulations In the case of an approved NDA, 314.8(d) [now 21 C.F.R. § 314.70(c)(2)(i)] permits the addition to the drug's labeling . . . of information about a hazard without advance approval by the FDA.

Id. (citing 21 Fed. Reg. 37,447 (1979)).

⁴⁶ *Id.* at 1095. After an ensuing three years of debate regarding whether to strengthen the antidepressant labeling, the FDA required manufacturers to place a stronger warning, known as a "black box" warning, on the labeling, highlighting the potential association between the drugs and the risk of suicide. Public Health Advisory, FDA, Worsening Depression and Suicidality in Patients Being Treated with Antidepressant (Mar. 22, 2004), available at <http://www.fda.gov/cder/drug/antidepressants/AntidepressantsPHA.htm> (recommending labeling for antidepressants like Zoloft be modified to reflect potential suicide risks); Press Release, FDA, FDA Launches a Multi-Pronged Strategy to Strengthen Safeguards for Children Treated with Antidepressant Medications (Oct. 14, 2004), available at <http://www.fda.gov/bbs/topics/news/2004/NEW01124.html> (black box warning required on SSRIs). The British equivalent of the FDA recommended a similar warning as early as 2002, before the FDA's pro-preemption position was made known. See Brief for Public Citizen as Amicus Curiae Supporting Plaintiff-Appellee at 6, *Motus*, 358 F.3d 659 (No. 02-55372), 2003 WL 22716063 [hereinafter *Motus* Amicus Brief of Public Citizen]. In May 2007, the FDA asked makers of the drugs to expand the warning labels yet again, to include risks of suicide to eighteen- to twenty-four-year-olds. Andrew Bridges, *FDA Warns of Suicide Risks Linked to Drug*, ASSOC. PRESS, May 3, 2007 (on file with the Boston College Law Review), available at http://www.bc.edu/schools/law/lawreviews/bclawreview/Past_Issues.html.

⁴⁷ *Motus* Amicus Brief of United States, *supra* note 37, at 13.

⁴⁸ *Id.* at 14.

der the FDCA.⁴⁹ Notably, however, the FDA must make a determination that a drug is misbranded and then seek injunctive relief from a federal district court before a final determination on misbranding results in the assessment of penalties.⁵⁰

A number of subsequent cases have addressed this specific issue.⁵¹ In *Colacicco v. Apotex, Inc.*, a 2006 case in the United States District Court for the Eastern District of Pennsylvania, the plaintiffs made similar claims regarding the failure to warn of increased risk of suicidality on labeling for Paxil, another SSRI, manufactured by GlaxoSmithKline and Apotex.⁵² Defendants moved for summary judgment on the same bases as had Pfizer in *Motus*. Unlike Pfizer, however, the *Colacicco* defendants were successful, in large part because the trial court deferred to the FDA's position in favor of preemption.⁵³ An increasing number of prescription drug labeling cases have been defended successfully on similar grounds.⁵⁴

Most cases, however, have denied preemption.⁵⁵ For example, *Perry v. Novartis Pharma. Corp.*, another 2006 case from the United States District Court for the Eastern District of Pennsylvania, concluded that the federal law did not preempt the plaintiffs failure-to-warn claims because a state law requirement to provide an additional warning would not force the drug company to choose between violating federal or state law.⁵⁶ The court noted that no federal law prevented the manufacturer from adding a warning of increased cancer risk to children who used

⁴⁹ *Id.* at 16.

⁵⁰ 21 U.S.C. § 332 (2000); see also *Motus* Amicus Brief of Public Citizen, *supra* note 46, at 16 (arguing that threat of enforcement action not enough to create a conflict; filing of enforcement does not guarantee that the FDA will prevail). The manufacturer is entitled to a jury trial of the issue. 21 U.S.C. § 332(b).

⁵¹ See, e.g., *Colacicco*, 432 F. Supp. 2d at 525–35.

⁵² *Id.* at 519–20.

⁵³ *Id.* at 525–35.

⁵⁴ *Needleman*, 2004 WL 1773697, at *5 (Zolof warning litigation); *Dusek*, 2004 WL 2191804, at *10 (Zolof warning litigation); *Abramowitz v. Cephalon, Inc.*, 2006 WL 560639, at *4 (N.J. Super. Ct. Law Div. Mar. 3, 2006) (Actiq warning litigation).

⁵⁵ *In re Vioxx Prods. Liab. Litig.*, No. MDL 1657, 2007 WL 1952964, at *10 (E.D. La. July 3, 2007); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 291 (E.D.N.Y. 2007); *Perry*, 456 F. Supp. 2d at 688; *Laisure-Radke, Inc.*, 426 F. Supp. 2d at 1174 (Prozac warning litigation); *Jackson*, 432 F. Supp. 2d at 969 (Zolof warning litigation); *Peters*, 417 F. Supp. 2d at 1058 (Prilosec warning litigation); *Witczak*, 377 F. Supp. 2d at 732 (Zolof warning litigation); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1044 (S.D. Ill. 2001) (Parlodol lactation suppressant warning litigation); *Coutu v. Tracy*, No. C.A. PC/00-3720, 2006 WL 1314261, at *4 (R.I. Super. May 11, 2006) (Propofol coma-inducing drug warning litigation).

⁵⁶ 456 F. Supp. 2d at 685.

Elidel, an eczema treatment.⁵⁷ The court recognized that state law tort lawsuits provide an important backstop to the federal regulatory scheme.⁵⁸ In addition, the court was persuaded by the absence of an FDA rejection of the particular warning the plaintiffs sought, as well as the ability of manufacturers to modify their labeling without FDA approval.⁵⁹

When it applies, federal preemption doctrine acts like a “super” government compliance defense because it permits complete displacement of state law by the federal regulation. Because implied conflict preemption doctrine requires an assessment of federal regulatory objectives to determine whether an actual conflict exists with the operation of applicable state laws,⁶⁰ an understanding of the regulatory scheme for prescription drug labeling and the objectives served is critical, and is the subject of the next Part.⁶¹

II. LABELING REGULATIONS UNDER THE FEDERAL FOOD AND DRUG LAWS

This Part examines in greater detail the regulatory scheme under the FDCA, providing context for the preemption debate.⁶² It begins by describing the labeling requirements of the federal food and drug laws and then exploring how drug labeling is created, approved, and modified.⁶³ Finally, it details the FDA’s new regulation for drug labeling and its proposed preemptive effect.⁶⁴

A. Requirements of the Federal Food and Drug Laws

Federal regulation of food and drugs occurred as early as the mid-nineteenth century but began in earnest in 1906 with the enactment of

⁵⁷ *Id.*

⁵⁸ *Id.* at 687.

⁵⁹ *Id.* at 686. The court also noted that other methods were available for manufacturers to use to communicate increased risks, in addition to the federally approved labeling, that would not be subject to preemption analysis. *Id.*

⁶⁰ *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714–16 (1985) (discussing implied preemption requirements); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (discussing assessment of federal objectives in implied preemption inquiry). See generally Davis, *supra* note 15, at 969–71, 990–97 (discussing implied conflict preemption).

⁶¹ See *infra* notes 62–148 and accompanying text.

⁶² See *infra* notes 65–148 and accompanying text.

⁶³ See *infra* notes 65–111 and accompanying text.

⁶⁴ See *infra* notes 112–148 and accompanying text.

the Pure Food and Drug Act.⁶⁵ The 1906 Act was prompted by concerns raised by state food and drug regulators over adulterated and misbranded food products moving in interstate commerce and contaminating the food and drug supply.⁶⁶ The states had regulated the safety of food and drugs since the earliest days of the United States's history.⁶⁷ State regulators encouraged, indeed implored,⁶⁸ the national government to create a federal agency to aid in regulation because of concerns over the states' inability to reach the interstate sale of fraudulent products and, thus, to protect consumers from them.⁶⁹

The modern version of the federal food and drug regulatory scheme dates from the Food, Drug and Cosmetic Act of 1938.⁷⁰ Congress adopted the 1938 Act to protect the public health by enforcing certain standards of purity and effectiveness, and also to prevent the sale of misbranded or adulterated products.⁷¹ The 1938 legislation extended control over more products and enlarged and stiffened the penalties for disobedience.⁷² In 1962, Congress passed the Kefauver-Harris Amendments to add the requirement of drug efficacy, mandate greater safety, and introduce a rigorous new drug approval process.⁷³ Several amendments to the 1938 Act over the ensuing years have

⁶⁵ For a history of the early regulation of food and drugs in the United States, see 1 JAMES T. O'REILLY, *FOOD AND DRUG ADMINISTRATION* §§ 3:1-4 (2d ed. 2005).

⁶⁶ *Id.* § 3:2.

⁶⁷ 2 O'REILLY, *supra* note 65, § 25:1.

⁶⁸ See C. C. Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 LAW & CONTEMP. PROBS. 3 (1933); see also 2 O'REILLY, *supra* note 65, § 25:1. For additional discussion of the history of the FDCA, see FDA History, <http://www.fda.gov/oc/history>; and Milestones in U.S. Food and Drug Law History, <http://www.fda.gov/opacom/backgrounders/miles.html>.

⁶⁹ See 2 O'REILLY, *supra* note 65, at § 25:1 (overview of relationship between the FDA and state governments).

⁷⁰ Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301-397 (West 1999 & Supp. 2007).

⁷¹ *Id.* § 331 (describing prohibited acts of adulteration and misbranding). See generally *United States v. Sullivan*, 332 U.S. 689 (1948) (discussing purposes of FDCA); *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914) (discussing similar purposes of predecessor Pure Food and Drug Act of 1906); *United States v. Diapulse Corp.*, 457 F.2d 25 (2d Cir. 1972) (discussing purposes of Act to prevent adulterated and misbranded food and drugs); *Pharm. Mfrs. Ass'n v. Food & Drug Admin.*, 484 F. Supp. 1179 (D. Del. 1980) (same); Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER, Jan./Feb. 2006, available at http://www.fda.gov/fdac/features/2006/106_cder.html.

⁷² See *United States v. Dotterweich*, 320 U.S. 277, 282 (1943); *Research Labs. v. United States*, 167 F.2d 410, 421 (9th Cir. 1948).

⁷³ Kefauver-Harris Amendments to FDCA, Pub. L. No. 87-781, 76 Stat. 780 (1962); see Meadows, *supra* note 71, at 1 ("Before marketing a drug, firms now had to prove not only safety, but also provide substantial evidence of effectiveness for the product's intended use. . . . Also critically, the 1962 amendments required that the FDA specifically approve the marketing application before the drug could be marketed, another major change.").

added to the complexity of the regulatory scheme and heightened the FDA's ability to achieve its public safety goals.⁷⁴

The key protection against the marketing of ineffective or unsafe prescription pharmaceutical products comes from the New Drug Approval process, which a company must complete before it can market a drug.⁷⁵ Once a drug is approved and on the market, fewer regulations exist to enable the FDA to follow the experience of an approved drug's users. An office responsible for policing the postmarketing safety of prescription drugs, the Drug Safety Oversight Board (the "DSOB"), was created in 2005, in part as a result of the perceived lack of action by the FDA in response to information regarding an increased risk of serious side effects in those using the osteoarthritis drug Vioxx.⁷⁶ The U.S. Gov-

For a discussion of drug efficacy requirements, see generally Anita Bernstein & Joseph Bernstein, *An Information Prescription for Drug Regulation*, 54 BUFF. L. REV. 569 (2006).

⁷⁴ See, e.g., Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-28, tit. 2, § 201, 118 Stat. 891, 905; Best Pharmaceuticals for Children Act, Pub. L. No. 107-109, § 1, 115 Stat. 1408, 1408 (2002); Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 1(a), 108 Stat. 4325, 4325; Nutrition Labeling and Education Act Amendments of 1993, Pub. L. No. 103-80, § 1, 107 Stat. 773, 773; Medical Device Amendments of 1976, Pub. L. No. 94-295, § 1(a), 90 Stat. 539, 539.

⁷⁵ 21 U.S.C. § 355 (2000 & Supp. III 2003) (new drug application requirements); see also Applications for FDA Approval to Market New Drugs, 21 C.F.R. pt. 314 (regulations for new drug approval applications). The Center for Drug Evaluation and Research (the "CDER") is the office primarily responsible for evaluating new drug approval applications and is the self-described "consumer watchdog for the roughly 11,000 drugs on the market." Meadows, *supra* note 71, at 1. Within the CDER, an Office for New Drug Approval oversees the process. For an explanation of the organization of the CDER and the Office of New Drugs, see FDA, Ctr for Drug Evaluation and Research, Office of New Drugs Reorganization (June 22, 2005), http://www.fda.gov/cder/cderorg/ond_reorg.htm. For an explanation of the application process see FDA, Ctr. for Drug Evaluation and Research, Drug Approval Application Process (Feb. 2, 2006), <http://www.fda.gov/cder/regulatory/applications/default.htm>. Stories about the expense of the drug application process are legendary and are the backdrop to many calls for reform of the process. See, e.g., Clifton Leaf, *How Our National Obsession with Drug Safety Is Killing People—And What We Can Do About It*, FORTUNE, Feb. 20, 2006, at 107.

⁷⁶ See Press Release, FDA, FDA Statement on Vioxx and Recent Allegations and the Agency's Continued Commitment to Sound Science and Peer Review (Nov. 14, 2004), available at <http://www.fda.gov/bbs/topics/news/2004/NEW01136.html>. See generally *Ensuring Drug Safety: Where Do We Go from Here?: Hearing on Examining the Food and Drug Administration's Process of Ensuring Drug Safety Before the S. Comm. on Health, Education and Pensions*, 109th Cong. (2005) [hereinafter *Ensuring Drug Safety*]; *FDA's Drug Approval Process Up to the Challenge?: Hearing on Examining Food and Drug Administration's (FDA) Drug Approval Process, Focusing on FDA's Drug Approval Process After a Sponsor Demonstrates That Their Benefits Outweigh Their Risks for a Specific Population and Use, and That the Drug Meets Standards for Safety and Efficacy Before the S. Comm. on Health, Education and Pensions*, 109th Cong. (2005); Press Release, FDA, FDA Improvements in Drug Safety Monitoring (Feb. 15, 2005), available at <http://www.fda.gov/oc/factsheets/drugsafety.html> (explaining that the "emboldened vision" of the FDA includes that the DSOB will oversee management of drug safety

ernment Accountability Office (the "GAO") recently criticized the DSOB as being underfunded, understaffed, and lacking a clear and effective method to decide whether and how to act when it finds that a drug is unsafe.⁷⁷

If a prescription drug manufacturer fails to comply with any applicable regulation, the approved prescription drug may be considered misbranded or adulterated under the FDCA.⁷⁸ Penalties for selling an adulterated or misbranded drug or device may be assessed against the seller,⁷⁹ and include the seizure of noncompliant products⁸⁰ and injunctive relief.⁸¹ The FDA must have sufficient information on which to base an action for misbranding. Manufacturers are not required to report the results of the postmarketing clinical trials.⁸²

To be misbranded, a regulated product's labeling must be false or misleading in any particular.⁸³ Proper labeling includes certain identifying information, such as the name and place of business of the manufacturer, and prominent placement of information on the label to ensure readability.⁸⁴ Most importantly, proper labeling includes adequate directions for use, adequate warnings against dangerous use, and sufficient warnings against unsafe dosage.⁸⁵

issues and provide emerging information to health providers and patients about the risks and benefits of medicines).

⁷⁷ GAO-06-402, *DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POST-MARKETING DECISION-MAKING AND OVERSIGHT PROCESS* 1, 6 (2006) [hereinafter *GAO REPORT, DRUG SAFETY*], available at <http://www.gao.gov/new.items/d06402.pdf>. The GAO Report, prepared at the request of Congress, states: "The FDA lacks clear and effective processes for making decisions about providing management oversight of post-marketing safety issues." *Id.* at 5. The GAO Report concluded that the FDA needed increased legal authority to require post-marketing clinical trials to obtain risk information, describing "serious limitations in the data" that currently support post-marketing safety initiatives." *Id.* at 36. Congress recently enacted the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, in part "to enhance the postmarket authorities of the FDA with respect to the safety of drugs." Title IX, section 901, authorizes the FDA to require postmarket studies in some cases. *Id.* § 901.

⁷⁸ 21 U.S.C. § 351 (2000) (adulterated drugs and devices defined); 21 U.S.C.A. § 352 (West 1999 & Supp. 2007) (misbranded drugs and devices defined).

⁷⁹ 21 U.S.C. § 333 (2000 & Supp. III 2003).

⁸⁰ *Id.* § 334.

⁸¹ *Id.* § 332.

⁸² Leaf, *supra* note 75, at 120 ("PhRMA, the industry's powerful trade group, continues to fight the idea of mandatory reporting, but promises that its member companies will offer more data voluntarily.")

⁸³ 21 U.S.C. § 352(a).

⁸⁴ *Id.* § 352(b), (c). FDA-approved labeling is defined generally at 28 U.S.C. § 321(m). Proper labeling also includes the established name of the drug and information on the proportion of active ingredients and their established names, if any. *Id.* § 352(e).

⁸⁵ *Id.* § 352(f).

This labeling is directed at health care practitioners because prescription drugs require professional supervision by a practitioner licensed to administer such drugs.⁸⁶ A physician acts as the “learned intermediary” between the manufacturer and the patient—the patient is intended to use and benefit from the drug but needs a physician to assess the risk and possible benefit of the product for the patient’s condition.⁸⁷ Tort liability for prescription drugs is based primarily on allegations that the labeling contains inadequate warnings of risk or improper use resulting in insufficient advice to the prescribing physician about the potential harms of the drug.⁸⁸ The next Section explores how such warnings are created, approved, and modified through the FDA’s labeling approval process.⁸⁹

B. Prescription Drug Labeling Regulations

A number of sources are available for physicians to access information about the prescription drugs they may consider for treatment of their patients’ medical conditions.⁹⁰ A drug’s “labeling” is one of these sources. It refers to the set of documents from the manufacturer that accompany the drug when given to the prescribing physician and the

⁸⁶ *Id.* § 353(b).

⁸⁷ MADDEN AND OWEN ON PRODUCTS LIABILITY, *supra* note 10, § 22:8–:11, at 564–77. For criticism of the learned intermediary doctrine as it applies to widely advertised prescription drugs, see generally *Perez v. Wyeth Labs.*, 734 A.2d 1245 (N.J. 1999) (rejecting learned intermediary doctrine in case of direct to consumer advertised contraceptive device); and Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97 (2002).

⁸⁸ See MADDEN AND OWEN ON PRODUCTS LIABILITY, *supra* note 10, § 22:9, :10; see also *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (applying learned intermediary doctrine).

Liability for the defective design or formula of a prescription drug is not the subject of this Article. That topic is covered extensively elsewhere. See, e.g., RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (1998); RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k (1965). For a discussion of liability for defective drug design, see generally *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988); George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087 (2000); and James A. Henderson & Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE L.J. 151 (2000).

⁸⁹ See *infra* notes 90–111 and accompanying text.

⁹⁰ For example, the Physician’s Desk Reference, or PDR, is a compilation of the labeling inserts that accompany prescription drugs for easy physician access. As Madden and Owen explain, “The PDR is an annual publication, a compendium of information about all ethical drugs, which reproduces the information from the package inserts of all of them. The PDR is found in the offices of most United States physicians.” MADDEN AND OWEN ON PRODUCTS LIABILITY, *supra* note 10, § 22:11, at 574–76; see also Thompson Healthcare, PDR.net, <http://www.PDR.net> (last visited Oct. 9, 2007) (online version of the PDR).

end user.⁹¹ The FDA does not create the labeling, but it must ensure that the statutorily required information is adequately communicated to those users. Pursuant to the New Drug Approval regulations, the FDA approves proposed labeling provided to it by the manufacturer after review of the manufacturer's application.⁹² The FDA adopted a number of regulations to accomplish this task.⁹³

The FDA labeling regulations include general requirements on the content and format of labeling for prescription drugs.⁹⁴ The regulations also contain more specific requirements detailing what is to be included in the required labeling.⁹⁵ The specific requirements identify the data that the manufacturer must include, the order in which it must be included, and the indication and usage information that the manufacturer must provide.⁹⁶ The labeling regulations state that manufacturers must describe serious adverse reactions and potential safety hazards.⁹⁷ New drug applications are required to contain copies of the labeling proposed by manufacturers⁹⁸ as well as a summary of the contents of that labeling.⁹⁹

The FDA has described this labeling formation process as follows:

FDA's decision as to appropriate labeling is based on the evidence submitted by the applicant, as well as on the agency's review of other relevant information. Commonly, a drug manufacturer and FDA will discuss in detail the proposed drug labeling, including the various warnings to be placed on the product. Based on the known scientific evidence, appropriate warnings are drafted to express the known risks, while

⁹¹ 21 U.S.C. § 321(m) (2000 & Supp. III 2003); *see also* 1 O'REILLY, *supra* note 65, § 15:9.

⁹² 21 U.S.C. § 355 (defining application requirements for new drug approvals); *see also* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) ("A prescription drug product's FDA-approved labeling . . . is a compilation of information about the product, approved by the FDA, based on the agency's thorough analysis of the new drug application (NDA) . . . submitted by the applicant.").

⁹³ *See* 21 C.F.R. § 201.56-.57 (2007).

⁹⁴ *Id.* § 201.56.

⁹⁵ *Id.* § 201.57.

⁹⁶ *Id.* § 201.57(a), (b), (c), (d).

⁹⁷ *Id.* § 201.57(e), (f).

⁹⁸ 21 C.F.R. § 314.50(e)(2)(ii).

⁹⁹ *Id.* § 314.50(c)(2)(i).

avoiding the statement of unsubstantiated risks that may unnecessarily deter use of the drug.¹⁰⁰

Per this description, the labeling formulation process is one of give-and-take with oversight by the FDA.

Postapproval changes to labeling are permitted under certain circumstances.¹⁰¹ Manufacturers may make unilateral labeling changes without prior FDA approval to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not be proved.¹⁰² The FDA need not approve such labeling before the manufacturer implements it under this regulation, but the manufacturer must submit a supplemental application, called a Supplemental Submission for Changes Being Effectuated, to effect the change.¹⁰³ Such a unilateral labeling change has been called a "safety valve" because it encourages the addition of new warnings when severe risks not anticipated when the drug was originally approved become known.¹⁰⁴ The FDA must ultimately approve the labeling change,¹⁰⁵ but the regulation was promulgated to allow drug-makers to strengthen label warnings quickly when evidence of new side-effects is discovered.¹⁰⁶ Nevertheless, manufacturers commonly do not implement labeling changes without FDA approval.¹⁰⁷ Typically, the FDA and

¹⁰⁰ *Motus Amicus Brief of United States*, *supra* note 37, at 5.

¹⁰¹ 21 C.F.R. § 314.70(b) ("Major" labeling changes require prior FDA approval; "major" changes include changes in the drug's formulation that affect its substance).

¹⁰² *Id.* § 201.80(e). This section of the regulation also provides the FDA with authority to require a "prominently displayed box" with particularly important warning or risk information whose location is specified by the FDA. *Id.* This is known as a "black box warning."

¹⁰³ *Id.* § 314.70(c)(6)(iii)(A); *see also* *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 729 (D. Minn. 2005) (discussing the process and effect of a Supplemental Submission for Changes Being Effectuated application).

¹⁰⁴ O'Reilly, *supra* note 18, at 293-94 ("FDA's regulations and policies encourage prompt action by the drug companies to improve their warnings when the data justifies such enhancements."); *see also* *Werner v. Upjohn Co., Inc.*, 628 F.2d 848, 859-60 (4th Cir. 1980).

¹⁰⁵ 21 C.F.R. § 314.70(c)(6)(iii).

¹⁰⁶ *Witczak*, 377 F. Supp. 2d at 729 (citing 30 Fed. Reg. 993 (Jan. 30, 1965) and 44 Fed. Reg. 37,447 (June 26, 1979)); *see also* *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1033-34 (S.D. Ill. 2001) (discussing manufacturer's ability to supplement warnings under FDA regulations).

¹⁰⁷ *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (discussion of labeling procedures in comments to new labeling regulation); *see also* *Motus Amicus Brief of United States*, *supra* note 37, at 17 (discussing ultimate FDA approval required for all labeling changes).

the manufacturer negotiate about any contemplated labeling change prior to implementation.¹⁰⁸

In the preamble to its new labeling regulation, the FDA takes the position that most approved labeling preempts state common law tort actions, despite the manufacturer's obligation to alter labeling when additional safety information is acquired.¹⁰⁹ The manufacturer, therefore, is not placed in the position of having to change labeling in response to possible tort liability, but instead may rest on prior FDA approval of labeling.¹¹⁰ This new regulation and its attempt to affect preemption doctrine are discussed in the next Sections.¹¹¹

C. New Regulation on Labeling for Prescription Drugs

In 2006, the FDA issued a regulation that alters the requirements for the labeling of prescription drugs and is intended to make that labeling more clear, concise, and usable for physicians and patients.¹¹² The 2006 regulation introduces three changes: it (1) introduces a "Highlights" section to labeling, which will provide immediate access to a drug's most commonly referenced material;¹¹³ (2) reorders and reorganizes the contents of labeling, introducing graphical requirements;¹¹⁴ and (3) makes warning and adverse reaction information more accessible.¹¹⁵ The regulation applies to new drugs and those approved after 2001.¹¹⁶

¹⁰⁸See GAO REPORT, DRUG SAFETY, *supra* note 77, at 10.

¹⁰⁹ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934-35.

¹¹⁰ *Id.* at 3935.

¹¹¹ See *infra* notes 112-148 and accompanying text.

¹¹² Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3922; see also Press Release, FDA, FDA Announces Final Rule on the Requirements for Prescribing Information for Drug and Biological Products (Jan. 18, 2006), available at <http://www.fda.gov/cder/regulatory/physlabel/summary.pdf>. The labeling regulation change was prompted by "an increase in the length, detail, and complexity of prescription drug labeling, making it harder for health care practitioners to find specific information and to discern the most critical information." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3922.

¹¹³ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3923.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 3925. To assist manufacturers in complying with the new regulation, the FDA has produced four guidance documents in addition to the almost 200-page regulation with comments. *Id.* at 3929. Guidance documents are authorized to provide additional informa-

The regulation lists the general categories of information to be placed into the new "Highlights" section including "Boxed Warning," "Recent Major Changes," "Indications and Usage," "Contraindications," and "Warnings and Precautions."¹¹⁷ The drug manufacturer chooses the information to be included in each section, including the "Warning and Precautions" section.¹¹⁸ The regulation instructs that "judgment will continue to be necessary" in deciding which information must be emphasized.¹¹⁹

Physicians and health care practitioners expressed unequivocal enthusiasm for the "Highlights" section, whereas manufacturers were either opposed or strongly opposed to it.¹²⁰ Manufacturer opposition was based, in part, on the obligation to choose what important warnings or other information to include and what information to omit; an incorrect choice might cause the labeling to be misleading.¹²¹ Consistent with its predecessor, the new regulation requires manufacturers to revise labeling unilaterally to include warnings about clinically significant hazards as soon as there is reasonable evidence of a causal association with the drug.¹²² This language is slightly more rigorous than its

tion to regulated industries about compliance with FDA regulations and to inform the general public about FDA actions. 21 U.S.C. § 371(h)(1) (2000).

¹¹⁷ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3924.

¹¹⁸ *Id.* at 3930. FDA's guidance document on "Warnings and Precautions," intended to assist manufacturers with how to determine the contents of that section, states that it does not establish legally enforceable responsibilities. See FDA, Ctr. for Drug Evaluation and Research, Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warnings Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format (Jan. 18 2006), <http://www.fda.gov/cder/guidance/5538dft.htm> ("Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.").

¹¹⁹ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3932.

¹²⁰ *Id.* at 3930.

¹²¹ *Id.* Several comments suggested more specific criteria were needed to enable manufacturers to choose consistently the appropriate information to be included in the "Highlights" section. *Id.* at 3932. Manufacturers also expressed concern about potential competitive disadvantages that might result. *Id.* The FDA, acknowledging the concerns, suggested that it is "essential for FDA to review and approve most proposed changes to the information in Highlights" and consequently is revising its regulations on supplementing approvals. *Id.* The FDA is revising 21 C.F.R. § 314.70(c)(6)(iii), the "safety valve" mentioned earlier, *supra* notes 103–104, which permits a manufacturer to alter a label to introduce important safety information. *Id.*

¹²² 21 C.F.R. § 201.56(a)(5) (2007) ("In accordance with § 314.70 . . . the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established.").

predecessor in that it requires evidence of a clinically significant hazard connected with a drug before changing approved labeling, though a causal relationship still is not required.¹²³ Manufacturers continue to have permission to add risk information to the Full Prescribing Information without first obtaining FDA approval.¹²⁴

Manufacturers maintain discretion under the new regulation to choose what to say in drug labeling and how to say it with FDA oversight, as before.¹²⁵ Perhaps it is this necessary exercise of manufacturer discretion that prompted the FDA to include a section in the preamble about the product liability implications of the proposed rule.¹²⁶

D. *Proposed Preemptive Effect of the New Labeling Regulation*

The FDA favored the concurrent operation of state tort law for almost the entire first century of its existence based on its inability to anticipate every way a consumer could be injured by the products it regulated and on the lack of a federal remedy to provide redress for injured consumers.¹²⁷ In the preamble to the new labeling regulation, however, the FDA now argues that product liability lawsuits have directly threatened the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs.¹²⁸

¹²³ For a discussion of former labeling regulation, see *supra* note 102 and accompanying text.

¹²⁴ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934, 3969.

¹²⁵ *Id.* at 3930, 3932.

¹²⁶ *Id.* at 3933.

¹²⁷ *Motus Amicus* Brief of Public Citizen, *supra* note 46, at 12. The Public Citizen Litigation Group argued that:

when Congress was considering legislation that ultimately was enacted as the Food, Drug, and Cosmetic Act of 1938, it made its intentions clear. Congress specifically rejected a proposal to include a private right of action for damages caused by faulty or unsafe products regulated under the Act on the ground that such a right of action already existed under state common law.

Id. (citing *Hearings Before Subcomm. of Comm. on Commerce on S. 1944*, 73d Cong., 2d Sess. 400, 403 (1933)); see also *Borden Co. v. Liddy*, 200 F. Supp. 221, 225 (S.D. Iowa 1961) (explaining that federal food labeling regulations provided a minimum level of safety that could be supplemented by more stringent state regulations).

¹²⁸ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934. The FDA cites three cases in support of this proposition. *Dowhal v. SmithKline Beecham Consumer Healthcare* found conflict preemption based on a FDA warning on nicotine replacement therapy drugs despite a savings clause in the statute specifically protecting the state requirement. 83 P.3d 1, 15 (Cal. 2004). *Motus v. Pfizer, Inc.* was resolved in favor of the manufacturer on causation. 358 F.3d 659, 661 (9th Cir. 2004). *In re Paxil Products Liability Litigation* is an ongoing multidistrict litigation con-

The FDA has explicitly called for preemption before, in implementing the Medical Device Amendments (the "MDA") of 1976 to the FDCA,¹²⁹ but Congress included an express preemption provision in the MDA that delegated authority to the FDA to assess the preemptive effect that its regulations would have on state laws.¹³⁰ By contrast, the FDA does not have express authority to preempt regarding prescription drug labeling, and the agency specifically did not address preemption in the proposed new drug labeling regulation.¹³¹ Rather, the original commentary to the regulation specifically stated that it did not preempt state law and that, therefore, it did not implicate federalism concerns.¹³² The final regulation also does not contain a preemption provision, but rather discusses preemption in the "preamble" section.¹³³ That discussion endorses the litigation positions taken in *Motus* and other cases¹³⁴ and suggests that preemption of state tort law is the FDA's "long standing view" on preemption.¹³⁵ That description is at odds with prior statements of the FDA.¹³⁶

The regulation's preamble, which is in essence an advisory opinion,¹³⁷ argues that state law tort actions may frustrate the agency's im-

solidated proceeding. 296 F. Supp. 2d 1374, 1375 (J.P.M.L. 2003). None of these three cases would seem to give cause for alarm.

¹²⁹ 21 U.S.C. § 360k (2000) (express preemption provision of Medical Device Amendments of 1976); 21 C.F.R. § 808.1-.5 (2007) (regulations implementing preemption provision). For a discussion of preemption under the Medical Device Amendments, see *infra* notes 236-263 and accompanying text.

¹³⁰ 21 U.S.C. § 360k(a); see *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496-97 (1996) (discussing FDA regulation implementing preemption provision of MDA).

¹³¹ See Catherine Hollingsworth & Dana A. Elfin, *FDA Revises Labeling Format for Drugs*, 34 BNA PRODS. SAFETY & LIAB. REP. 52, 52 (2006).

¹³² Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (explaining that labeling rule does not have federalism implications nor does it preempt state law; preemption assessment required by Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999)).

¹³³ See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3969.

¹³⁴ *Id.* at 3934 ("In order to more fully address the comments expressing concern about the product liability implications of revising the labeling for prescription drugs, we believe it would be useful to set forth in some detail the arguments made in those amicus briefs.").

¹³⁵ *Id.*

¹³⁶ See *supra* note 32 and accompanying text. The National Conference on State Legislatures has expressed opposition "to the inclusion of language that would preempt state product liability laws" in the final regulation and to the process by which the preemption language was included. See Letter to Mike Leavitt, *supra* note 35.

¹³⁷ 21 C.F.R. § 10.85(d)(1) (2007); see also *Perry v. Novartis Pharm. Corp.*, 456 F. Supp. 2d 678, 683-84 (E.D. Pa. 2006) (discussing effect of preamble).

plementation of federal objectives.¹³⁸ The FDA disagrees with the assertion—widely made—that its labeling requirements are minimum safety standards and describes that characterization as a misunderstanding of the Act.¹³⁹ The FDA takes the position that its regulations can establish both a floor and a ceiling.¹⁴⁰ Such circumstances include when additional labeling requirements may not be more protective of patients, but rather “erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use.”¹⁴¹ The FDA expresses concern that “[e]xaggeration of risk could discourage appropriate use of a beneficial drug” and thus cause over-warning.¹⁴²

After articulating the arguments in favor of preemption, the FDA identifies those claims that its new labeling regulation would impliedly preempt.¹⁴³ It seeks to codify its position in *Motus* that if a label were proposed to the FDA and ultimately not required by the time the plaintiff claims it should have been, the plaintiff’s claim based on a failure to warn is preempted.¹⁴⁴ The FDA acknowledges that some state common law damages actions will not be preempted.¹⁴⁵ It does

¹³⁸ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934.

¹³⁹ *Id.* at 3934–35.

¹⁴⁰ *Id.* at 3935. As will be seen *infra* notes 278–295 and accompanying text, this argument appears derived from the Supreme Court’s recent implied preemption case, *Geier v. American Honda Motor Co.*, which found a motor vehicle safety standard to be both a floor and a ceiling and thus preemptive of state common law damages actions. 529 U.S. 861, 868 (2000).

¹⁴¹ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935. To illustrate the over-warning concern, the preamble uses a case in which a state court found federal preemption of an inconsistent state regulation, not a product liability action. *Id.* Ironically, the over-warning concern was raised in *Motus* and other Zolof cases in support of preemption, but ultimately the FDA required a stronger warning of the heightened risk of suicidality, which it had earlier rejected. See *supra* note 46 and accompanying text.

¹⁴² Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935; see also *Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004) (discussing over-warning concern in context of medical device preemption).

¹⁴³ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935–36. It protects manufacturers for the discretionary choices they make about what to include in the new “Highlights” section of the regulation. *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.* at 3936 (explaining that state common law damages actions based on parallel state requirements will not be preempted). In addition, in a recent amicus brief in *Perry v. Novartis Pharmaceuticals Corp.*, the FDA acknowledged that it does not assert that any failure-to-warn claim premised on a manufacturer’s failure to provide a warning not con-

not address, however, the potentially complementary way in which common law damages actions may operate concurrently with FDA regulations by permitting compensation for injury and thereby creating an additional incentive for public safety.¹⁴⁶

The FDA claims that existing preemption principles support its preemption position.¹⁴⁷ The FDA appears to be attempting to alter its historic position against preemption and apply its new position retroactively. To assess the effect of such an attempt requires a thorough understanding of preemption doctrine, which is explored in the next Part.¹⁴⁸

III. PREEMPTION UNDER THE FEDERAL FOOD AND DRUG LAWS

This Part explores the evolution of express and implied preemption doctrine.¹⁴⁹ It then distills from the case law principles important in understanding preemption of food and drug regulation.¹⁵⁰

A. Early Preemption Doctrine Under the Food and Drug Laws

Shortly after enactment of the first federal food and drug law in 1906,¹⁵¹ questions arose regarding how much state authority it displaced. In 1912, in one of the earliest preemption cases, *Savage v. Jones*, the U.S. Supreme Court was asked to determine whether a state law permitting additional regulation was preempted, even though the federal legislation arguably did not apply to the food additive at issue.¹⁵² The Court noted that Congress did not expressly declare its intention to prevent the states from regulating within the subject of food and drugs.¹⁵³ The Court then described the applicable implied preemption inquiry:

tained in the drug's approved labeling is preempted. Amicus Curiae Letter Brief of FDA to Judge Stewart Dalzell at 10–11, *Perry*, 456 F. Supp. 2d 678 (No. CIV-A 05-5350) (E.D. Pa. Sept. 21, 2006).

¹⁴⁶ See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935.

¹⁴⁷ *Id.* at 3935–36.

¹⁴⁸ See *infra* notes 149–348 and accompanying text.

¹⁴⁹ See *infra* notes 151–339 and accompanying text.

¹⁵⁰ See *infra* notes 340–348 and accompanying text.

¹⁵¹ Federal Food and Drugs Act of 1906, Pub. L. No. 59-385, 34 Stat. 768, (repealed 1938).

¹⁵² 225 U.S. 501, 509 (1912). The seller of the food additive claimed that it was marketed as an herbal treatment for animals, not as feed, and consequently escaped federal regulations. *Id.* at 511. Further, because Congress had regulated in the field, the seller argued that the states were entirely foreclosed from regulating. *Id.* at 512.

¹⁵³ *Id.* at 533.

If the purpose of the [federal] act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power.

But the intent to supersede the exercise by the State of its police power as to matters not covered by the Federal legislation is not to be inferred from the mere fact the Congress has seen fit to circumscribe its regulation and to occupy a limited field. In other words, such intent is not to be implied unless the act of Congress fairly interpreted is in *actual conflict* with the law of the state.¹⁵⁴

The Court concluded that the state statute was not impliedly preempted because of two corollary principles the Court articulated: (1) Congress's implied purpose to preempt must be clearly manifested, and (2) the repugnance or conflict between the congressional purpose and the state regulation must be "direct and positive" such that the two acts could not be reconciled.¹⁵⁵ The state statute was found not to be in actual conflict with the federal regulation because it did not impose conflicting standards nor oppose federal authority—rather, it added consistent, but more rigorous, regulation.¹⁵⁶

Savage was decided decades before the onslaught of post-Depression-era economic regulation and post-World-War-II civil rights and other public interest legislation.¹⁵⁷ Preemption doctrine was in its infancy. Nevertheless, *Savage* is an important foundational case because it articulated a rigorous implied conflict preemption analysis in an early food and drug labeling matter.¹⁵⁸ Indeed, the Court continues to refer

¹⁵⁴ *Id.* (citations omitted) (emphasis added).

¹⁵⁵ *Id.* at 537. The Court relied for support on a case holding that a state statutory action for civil damages for transporting diseased cattle was not preempted by a federal statute regulating the animal industry because there was no obstruction of the purposes of Congress by permitting the states to impose civil damages. *Id.* at 536–37. The Court stated:

May not these statutory provisions stand without obstructing or embarrassing the execution of the act of congress? This question must of course be determined with reference to the settled rule that a statute enacted in execution of a reserved power of the state is not to be regarded as inconsistent with an act of congress . . . unless the repugnance or conflict is so direct and positive that the two acts cannot be reconciled or stand together.

Id. at 535 (quoting *Mo., K. & T. Ry. Co. v. Haber*, 169 U.S. 613, 624 (1898)).

¹⁵⁶ *Id.* at 539.

¹⁵⁷ *Savage*, 225 U.S. at 501.

¹⁵⁸ *Id.* at 535–37.

to *Savage's* implied conflict preemption analysis, suggesting its continuing influence.¹⁵⁹

Building on its discussion of implied preemption in *Savage*, the Court, in 1913, decided *McDermott v. Wisconsin*, in which it found a state food labeling statute impliedly preempted for two reasons.¹⁶⁰ First, the Wisconsin statute required the defendant food-seller to remove a complying federal label to satisfy the state statute, rendering the product misbranded under federal law.¹⁶¹ Second, the U.S. Secretary of Agriculture had decided that the defendant's label was satisfactory, permitting the conclusion that compliance with the state law would render the product misbranded under federal law.¹⁶² The Court concluded that the state's attempt to regulate *exclusively* was an improper interference with Congress's authority.¹⁶³ The Court, conceding the state's authority to regulate consistent with federal law, concluded that the state could not destroy rights arising out of the federal statute nor impair the effect of a federal law.¹⁶⁴ The impossibility of dual compliance required defeat of the state law.¹⁶⁵

Thus, *Savage* and *McDermott* contain the seeds of the implied conflict preemption doctrine the Court applies today.¹⁶⁶ Unlike those cases, however, preemption doctrine during the years between the early twentieth century and the mid-twentieth century is generally marked by a more generous attitude toward state regulation.¹⁶⁷ During this time, the Supreme Court defined implied preemption doctrine more clearly.¹⁶⁸ Between the 1940s and 1980s, implied preemption doctrine coalesced

¹⁵⁹ *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (explaining that foreign affairs power and the congressional Burma Act impliedly preempted Massachusetts's Burma law); see also Davis, *supra* note 15, at 1012 (noting the re-emergence of *Savage* in Court's modern preemption cases).

¹⁶⁰ *McDermott v. Wisconsin*, 228 U.S. 115, 133 (1913).

¹⁶¹ *Id.* The U.S. Secretary of Agriculture had concluded that the defendant's corn syrup label was in compliance with the federal statute's misbranding provision. *Id.* at 127.

¹⁶² *Id.* at 133.

¹⁶³ *Id.* at 134.

¹⁶⁴ *Id.* at 133–34.

¹⁶⁵ *McDermott*, 228 U.S. at 133–24. The “impossibility” category of implied preemption, thus, has its roots in cases like *McDermott*. See *id.* The Court has rarely found true impossibility, however. See, e.g., *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963) (discussing implied preemption involving impossibility); see also Davis, *supra* note 15, at 984–85.

¹⁶⁶ See *McDermott*, 228 U.S. 133–34; *Savage*, 225 U.S. at 533.

¹⁶⁷ Davis, *supra* note 15, at 974–78.

¹⁶⁸ *Id.*

into the now-standard categories of occupation of the field preemption¹⁶⁹ and conflict preemption.¹⁷⁰

Conflict preemption occurs primarily when the state law "stands as an obstacle" to the accomplishment of federal objectives and, therefore, must yield.¹⁷¹ An early example is the Supreme Court's 1942 decision *Cloverleaf Butter v. Patterson*, in which Alabama officials seized substantial quantities of packing stock butter, claiming violation of state safety regulations, when the Federal Department of Agriculture would not have permitted seizure.¹⁷² The Court, relying on *Savage* and *McDermott*, concluded that the Alabama law was preempted.¹⁷³ The Court stated that for implied preemption to occur, "it must be clear that the federal provisions are inconsistent with those of the state to justify thwarting the state regulation."¹⁷⁴ Recognizing that the line distinguishing cases of inconsistency was narrow, the Court found the case to be more like *McDermott*, in which the state law prohibited what the federal law permitted.¹⁷⁵ The Court distinguished *Savage* because the state law at issue in that case merely required additional disclosures that the federal law neither required nor prohibited.¹⁷⁶ In *Savage*, federal law was agnostic on the value of the state regulation; in *McDermott* and *Cloverleaf Butter*, federal and state law appeared to operate in opposite directions.¹⁷⁷

Direct, positive, actual, clear: these words describe a substantial showing of conflict that must be made before implied preemption operates based on the Court's early cases.¹⁷⁸ As applied, the Court's finding of implied conflict preemption in *Cloverleaf Butter* seemed based on a

¹⁶⁹ Occupation of the field preemption occurs where Congress's legislation is so comprehensive that it occupies the entire field, displacing all state law. *Hines v. Davidowitz*, 312 U.S. 52, 74 (1941) (finding that the Alien Registration Act of 1940 occupied the field of foreign affairs and national treatment of aliens and was intended to be exclusive). The Court has rejected occupation of the field preemption under the FDCA. *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 717-18 (1985).

¹⁷⁰ See Davis, *supra* note 15, at 983-90.

¹⁷¹ See *Hillsborough County*, 471 U.S. at 713; *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Hines*, 312 U.S. at 67-68.

¹⁷² 315 U.S. 148, 150-51, 165-66 (1942).

¹⁷³ *Id.* at 158-59, 169.

¹⁷⁴ *Id.* at 156.

¹⁷⁵ See *id.* at 158-59.

¹⁷⁶ *Id.*

¹⁷⁷ *Cloverleaf*, 315 U.S. at 158-59.

¹⁷⁸ *Id.* at 156; *Savage*, 225 U.S. at 533, 537.

minimal conflict¹⁷⁹ and may reflect an intent to minimize clashes between regulating authorities to free young regulated industries from inconsistencies.¹⁸⁰ By contrast, the dissenting opinion in *Cloverleaf Butter* emphasized due regard for the maintenance of our dual system of government, which:

demands that the courts do not diminish state power by extravagant inferences regarding what Congress might have intended if it had considered the matter, or by reference to their own conceptions of a policy which Congress has not expressed and is not plainly to be inferred from the legislation which it has enacted.¹⁸¹

Sixty years later, similar arguments continue to be made on both sides of the preemption debate.

B. Modern Implied Preemption Cases

The Supreme Court did not address another FDCA preemption case until 1985, in *Hillsborough County v. Automated Medical Laboratories, Inc.*¹⁸² The Court did, however, decide a number of implied preemption cases in the intervening years that are worth noting.¹⁸³ In 1959, in *San Diego Building Trades Council v. Garmon*, the Court was faced for the first time with an argument for implied preemption of state common law damages actions.¹⁸⁴ In this case the question was whether the National Labor Relations Act preempted state tort actions by employers allegedly injured in the course of peaceful picketing by labor activists.¹⁸⁵ The Court spoke of the difficulty of ascertaining congressional intent when the enacting Congress, writing twenty-five years earlier, could not have foreseen the conflicts that would eventually arise.¹⁸⁶ In finding implied preemption based on a conflict with federal legislative objectives, the Court relied on two considerations: (1) the case involved na-

¹⁷⁹ See 315 U.S. at 172-73 (Stone, C.J., dissenting) (reasoning that there was a "complete want of conflict between the two statutes," and that the state statute "aids and supplements the federal regulation and policy").

¹⁸⁰ See *id.* at 167-69 (majority opinion).

¹⁸¹ *Id.* at 177 (Stone, C.J., dissenting).

¹⁸² 471 U.S. at 707.

¹⁸³ See generally *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984); *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236 (1959).

¹⁸⁴ 359 U.S. at 237-39.

¹⁸⁵ *Id.* at 241-45 (describing NLRA, as amended by the Labor Management Relations Act, 29 U.S.C. §§ 157, 158 (2000)).

¹⁸⁶ *Id.* at 239-40.

tional labor policy, about which Congress had legislated "with broad strokes,"¹⁸⁷ and (2) state regulation can be exerted through common law damages actions as effectively as through more direct regulatory means.¹⁸⁸ To this day, the Court continues to refer to *Garmon* for these propositions.¹⁸⁹ These two fundamental features of implied preemption analysis, defining the federal objectives with which state law arguably conflicts and assessing the regulatory nature of common law damages actions, are central to implied preemption analysis under the FDCA.¹⁹⁰

In the 1980s, the Court again addressed the impact of common law damages actions on implied preemption analysis. In its 1984 opinion in *Silkwood v. Kerr-McGee Corp.*, the Court was called upon to determine whether the Atomic Energy Act (the "AEA"),¹⁹¹ which regulated the nuclear energy industry, permitted state common law damages actions as a means of concurrent state regulation.¹⁹² The AEA gave states limited regulatory authority, which they had never had before.¹⁹³ The states were precluded, however, from regulating the safety aspects of nuclear material.¹⁹⁴ Thus, the preemption provision of the AEA carved out of federal dominion some small state regulatory authority.¹⁹⁵

The Supreme Court concluded unanimously that the AEA did not preempt the plaintiff's compensatory damages action.¹⁹⁶ The Court, after reviewing the legislative history and other congressional actions regarding the AEA,¹⁹⁷ found it difficult to believe that Congress would, without comment, remove all means of judicial recourse for those in-

¹⁸⁷ *Id.* at 240.

¹⁸⁸ *Id.* at 246-47. For a more complete discussion of the importance of *Garmon*, see Davis, *supra* note 15, at 981-83.

¹⁸⁹ See Davis, *supra* note 15, at 981-83, 1000.

¹⁹⁰ See *Garmon*, 359 U.S. at 240, 246-47.

¹⁹¹ 42 U.S.C.A. §§ 2011-2297h-13 (West 2003 & Supp. 2007). The AEA is administered by the Nuclear Regulatory Commission, formerly the Atomic Energy Commission. See *id.* at § 2073 (defining NRC authority). The AEA was enacted in 1954 to free the nuclear energy industry from total federal control and to provide for private involvement. Atomic Energy Act of 1954, Pub. L. No. 83-703, 68 Stat. 919, (codified as amended at 42 U.S.C.A. §§ 2011-2284).

¹⁹² 464 U.S. at 241. Karen Silkwood's estate alleged contamination with plutonium through irregularities at the Kerr-McGee Corp. nuclear power plant where she worked and sought personal injury and punitive damages under negligence and strict liability doctrines. *Id.* at 243.

¹⁹³ See generally *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190 (1983).

¹⁹⁴ 42 U.S.C.A. § 2021(c)(4).

¹⁹⁵ See *id.*

¹⁹⁶ *Silkwood*, 464 U.S. at 255-56. A majority of the Court held that the AEA similarly did not preempt the plaintiff's punitive damages claim. *Id.*

¹⁹⁷ *Id.* at 249-55.

jured by illegal conduct.¹⁹⁸ The Court recognized that common law damages actions have regulatory effect, but considered them consistent with federal objectives in the absence of clear congressional intent to prohibit them.¹⁹⁹ Recent decisions confirm the regulatory and remedial importance of common law damages actions.²⁰⁰

One year after *Silkwood*, the Court addressed a preemption challenge under the FDCA, though not one involving the regulatory effect of common law damages actions.²⁰¹ In *Hillsborough County*, a Florida county sought to regulate the collection of blood plasma from paid donors by requiring further limitations in addition to those required under federal regulations.²⁰² The defendant blood plasma center argued for preemption under both occupation of the field and conflict preemption.²⁰³ The Supreme Court disagreed on both issues and reversed an appellate court finding of preemption.²⁰⁴

The Court noted that the defendant "faces an uphill battle" in arguing for implied preemption.²⁰⁵ The hurdles to preemption fell into two categories: (1) prior agency position against preemption;²⁰⁶ and (2) the presumption that state or local regulation of matters related to health and safety can constitutionally coexist with federal regulation.²⁰⁷ These two impediments to preemption are central to the issue preemption in the drug labeling context and, therefore, must be fully understood.

The Court stated that the prior FDA position against preemption was dispositive on the question of implicit intent to preempt unless either the agency's position was inconsistent with clearly expressed

¹⁹⁸ *Id.* at 251. The Court stated:

Indeed, there is no indication that Congress even seriously considered precluding the use of such remedies either when it enacted the Atomic Energy Act in 1954 or when it amended it in 1959. This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct.

Id.

¹⁹⁹ *Id.* at 256.

²⁰⁰ See Davis, *supra* note 15, at 1001, 1013–14 (discussing the post-*Silkwood* treatment of common law damages actions in preemption analysis).

²⁰¹ *Hillsborough County*, 471 U.S. at 709.

²⁰² *Id.* at 709–10.

²⁰³ *Id.* at 714–16.

²⁰⁴ *Id.* at 716.

²⁰⁵ *Id.* at 714. Preliminarily, the Court confirmed that preemption of local ordinances is analyzed in the same way as the preemption of statewide laws. *Id.* at 714 n.1.

²⁰⁶ *Hillsborough County*, 471 U.S. at 714.

²⁰⁷ *Id.* at 715.

congressional intent, or subsequent developments revealed a change in that position.²⁰⁸ The FDA's position against preemption had been made clear in commentary to the blood collection regulations²⁰⁹ and even though the regulations had since been broadened, the FDA had not indicated that the new regulations affected its disavowal of any intent to preempt.²¹⁰ The Court thus rejected occupation of the field preemption even though the regulations were comprehensive,²¹¹ noting that "merely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements in the field,"²¹² consistent with the historic primacy of state regulation in matters of health and safety.²¹³

The Court's discussion of field preemption and the importance of the FDA's position against preemption also informed its rejection of implied conflict preemption.²¹⁴ The defendant had argued that the local ordinances embodied more stringent requirements than the federal law and, therefore, presented a serious obstacle to the federal goal of ensuring an adequate supply of plasma.²¹⁵ The Court found this concern to be too speculative to support preemption.²¹⁶ First, there was little evidence in the record to support the factual assertion of increased costs from the local regulations or the effect they would have on blood plasma collection.²¹⁷ Second, even if there had been evidence of increased costs to plasma collection operators and an in-

²⁰⁸ *Id.* at 714–15 (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–45 (1984)).

²⁰⁹ *Id.* at 714.

²¹⁰ *Id.* at 716–17. The Court states:

Thus, if an agency does not speak to the question of preemption, we will pause before saying that the mere volume and complexity of its regulations indicate that the agency did in fact intend to preempt [W]e will seldom infer, solely from the comprehensiveness of federal regulations, an intent to preempt in its entirety a field related to health and safety.

Id. at 718.

²¹¹ *Hillsborough County*, 471 U.S. at 716.

²¹² *Id.* at 717. The Court was "even more reluctant" to infer field preemption from regulations than from statutes, saying, "To infer preemption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive." *Id.*

²¹³ *Id.* at 719. Prior field preemption cases had involved a "special feature" supporting preemption—the foreign affairs power. *Id.* (citing *Hines*, 312 U.S. at 62).

²¹⁴ *Id.* at 720.

²¹⁵ *Id.*

²¹⁶ *Hillsborough County*, 471 U.S. at 720.

²¹⁷ *Id.* at 720–21.

creased burden on donors imposed under the local regulation, they did not necessarily interfere with the federal goal of maintaining an adequate plasma supply.²¹⁸ According to the Court, neither Congress nor the FDA had struck a balance between safety and quantity;²¹⁹ rather, the regulations that contemplated additional state and local requirements merely established minimum safety standards.²²⁰

Finally, the Court noted that the FDA could promulgate preemption regulations with relative ease, but it had not done so.²²¹ The Court attached significance to the absence of either an FDA position or formal regulation on preemption and, without such strong evidence, was reluctant to find a threat to the federal goal of ensuring sufficient plasma.²²² Because Congress had delegated to the FDA administration of the federal program, the Court was strongly influenced by the FDA's position as reflected in the prior regulatory commentary and the FDA's silence on the matter in the case before it.²²³

In summary, until the late 1980s, the Court found preemption under the FDCA only in two narrow cases, both essentially involving impossibility.²²⁴ Those cases arguably now rest on shaky ground because of the increasingly narrow definition of actual conflict the Court began to use in subsequent years.²²⁵ The Court certainly was influenced by the importance of historic state regulation in the area of public health and safety in all of these cases.²²⁶ After *Silkwood* and *Hillsborough County*, it would appear that common law damages actions would survive the implied conflict preemption hurdles defined by the Court, absent clear indication of agency position to the contrary. If the local regulations at issue in *Hillsborough County* did not create the kind of obstacle to federal objectives required for preemption, the more indirect regulation of common law damages actions would likely not be sufficient, particularly given the long tradition of permitting such actions.²²⁷

²¹⁸ *Id.* at 721.

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *Hillsborough County*, 471 U.S. at 721.

²²² *Id.*

²²³ *Id.*

²²⁴ See *supra* notes 160–166, 172–177 and accompanying text (discussing *McDermott* and *Cloverleaf Butter*).

²²⁵ See *supra* notes 191–199 and accompanying text (discussing *Silkwood*); see also Davis, *supra* note 15, at 983–90 (discussing narrowing of implied preemption doctrine during 1960s and 1970s).

²²⁶ See *Hillsborough County*, 471 U.S. at 715–16.

²²⁷ See *id.* at 716.

C. *The Rise of Express Preemption Doctrine and the FDCA:
Cipollone and Medtronic*

A short seven years after *Silkwood*, the Supreme Court reevaluated preemption doctrine as it applied to common law damages actions.²²⁸ In its 1992 decision in *Cipollone v. Liggett Group, Inc.*, the Court, applying preemption doctrine in a products liability action for the first time, concluded that where Congress has included an express preemption provision, and that provision provides a reliable indicium of congressional intent, the provision controls, and an implied preemption analysis is unnecessary.²²⁹ In such a case, the Court's task was only to determine the scope of the provision.²³⁰ Rarely had the Court given exclusive control to an express preemption provision, particularly as it applied to common law damages actions.²³¹

Because the FDCA does not contain an express preemption provision applicable to prescription drug labeling, *Cipollone* and subsequent cases involving express preemption are not vital to the required analysis. *Cipollone* did, however, represent a significant change in the approach to preemption doctrine, and subsequent cases have built on its greater focus on congressional intent and its treatment of the presumption against federal preemption of matters historically within the states' police powers.²³² The plurality opinion acknowledged that common law damages actions can have an indirect regulatory effect,²³³ but the dissenting Justices recognized that the Court's preemption cases had declined on several occasions to find the regulatory effects of state tort

²²⁸ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 508 (1992).

²²⁹ *Id.* at 517. *Cipollone* involved preemption of products liability claims involving cigarettes. *Id.* at 509-10. It required interpretation of the Federal Cigarette Labeling and Advertising Act (the "FCLAA") of 1965, Pub. L. No. 89-92, 79 Stat. 282 (codified as amended at 15 U.S.C. §§ 1331-1340 (2000)), and the Public Health Cigarette Smoking Act (the "PHCSA") of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331-1340). *Cipollone*, 505 U.S. at 530-31.

²³⁰ See *Cipollone*, 505 U.S. at 518, 523. The 1965 cigarette labeling act's preemption provision stated that "No statement relating to smoking and health . . . shall be required on cigarette packages or in advertising." *Id.* at 514 (quoting the FCLAA § 5(a)). The 1969 act changed the preemption provision slightly to state that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law" regarding cigarette labeling or advertising. *Id.* at 515 (quoting the PHCSA § 5(b)). The use of the phrase "requirement or prohibition" was critical to the Court's analysis of whether common law damages actions were prohibited. *Id.* at 522-24.

²³¹ See Davis, *supra* note 15, at 1001.

²³² See 505 U.S. at 516.

²³³ *Id.* at 524.

law either direct or substantial enough to warrant preemption.²³⁴ In the next several products liability preemption cases, the Court adhered to its focus on interpreting the scope of express preemption provisions and also confirmed the importance of implied preemption principles in the absence of Congress's explicit intent to preempt.²³⁵

The Court next decided an FDCA express preemption provision case in 1996, in *Medtronic, Inc. v. Lohr*.²³⁶ *Medtronic* involved application of the express preemption provision of the MDA.²³⁷ The MDA directs the FDA to regulate the safety and effectiveness of medical devices based on the type of device involved and the method by which it is approved for marketing.²³⁸ The express preemption provision in the MDA provides that states may not establish any requirement which is different from or in addition to any FDA imposed requirement regarding a device's safety or effectiveness.²³⁹ The defendant in *Medtronic* sought preemption of the plaintiff's design and manufacturing defect claims regarding its pacemaker because the device had been approved through a premarket notification process, which permits market approval if a device is substantially equivalent to one already on the market.²⁴⁰ The Court was divided on whether the MDA preempted the plaintiff's claims, but all Justices agreed that the express preemption provision controlled the analysis.²⁴¹

²³⁴ *Id.* at 537 (Blackmun, J., dissenting) (referencing *English v. Gen. Elec. Co.*, 496 U.S. 72 (1990); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174 (1988); and *Silkwood*, 464 U.S. 238).

²³⁵ *Freightliner Corp. v. Myrick*, 514 U.S. 280, 289–90 (1995) (interpreting the National Traffic and Motor Vehicle Safety Act, 15 U.S.C. § 1392(d) (current version at 49 U.S.C. § 30103(b)(1) (2000))); stating that there was no preemption because the federal agency had not promulgated the regulation addressing the product feature at issue); see also *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) (holding that the Federal Railroad Safety Act did not expressly preempt state common law damages actions based on the location of railroad crossing devices because Congress's intent clearly permitted more rigorous state regulation and rejecting agency interpretation of preemptive scope as inconsistent with the provisions' plain language).

²³⁶ 518 U.S. 470, 474 (1996).

²³⁷ 21 U.S.C.A. § 360k (West 1999 & Supp. 2007).

²³⁸ See *Medtronic*, 518 U.S. at 475–80 (detailing history of MDA and its regulatory scheme).

²³⁹ 21 U.S.C.A. § 360k(a).

²⁴⁰ 518 U.S. at 483.

²⁴¹ *Id.* at 484–85, 503 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Justice Stevens's plurality opinion suggested that actual conflict implied preemption analysis may be appropriate in certain circumstances even when an express preemption provision was at issue. *Id.* at 503 (plurality opinion) (citing *Freightliner Corp.*, 514 U.S. at 287).

Even though *Medtronic* involved express preemption analysis, a number of important features of the decision may affect implied conflict preemption under the FDCA.²⁴² First, the Court reiterated the historic primacy of state regulation to protect the health and safety of their citizens, which supports the great latitude states have had to govern in this area.²⁴³ The majority opinion confirmed that "we have long presumed that Congress does not cavalierly preempt state law causes of action."²⁴⁴ That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety.²⁴⁵ Consequently, the majority opinion considered the language of the express preemption provision narrowly.²⁴⁶ The premarket notification process, under which the pacemaker had been approved, did not contain device-specific requirements.²⁴⁷ Four Justices in the plurality opinion, therefore, concluded that nothing in the legislation, its history, or its basic purpose suggested that common law damages actions were intended to be requirements, noting the singularly odd word choice to accomplish a sweeping immunity.²⁴⁸ A majority of the Justices, however, concluded that common law damages actions generally do impose requirements, and, therefore, may be preempted under the statute if they differ from a clearly expressed federal requirement.²⁴⁹

Second, because the FDA had adopted a formal regulation to implement the preemption provision,²⁵⁰ all three *Medtronic* opinions explored the importance of the agency's position on determining the

²⁴² See *id.* at 475 (majority opinion); *id.* at 487–88 (plurality opinion); *id.* 495–96 (majority opinion).

²⁴³ *Id.* at 475 (majority opinion) (citing *Hillsborough County*, 471 U.S. at 719).

²⁴⁴ *Id.* at 485.

²⁴⁵ *Medtronic*, 518 U.S. at 485.

²⁴⁶ *Id.*

²⁴⁷ The pre-market notification requirement, also known as the 510k notification process, permits marketing of devices that are substantially equivalent to a device already on the market and is not as rigorous as the pre-market approval process required of entirely new devices. See *id.* at 476–80 (describing the processes and their differences). See generally SUSAN FOOTE, *MANAGING THE MEDICAL ARMS RACE: INNOVATION AND PUBLIC POLICY IN THE MEDICAL DEVICE INDUSTRY* (1992).

²⁴⁸ *Medtronic*, 518 U.S. at 487 (plurality opinion).

²⁴⁹ *Id.* at 505 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Justice Breyer, whose opinion provided the final vote against preemption, stated that express preemption provisions should be interpreted based on their "clear congressional command," if one exists. *Id.* at 505 (Breyer, J., concurring). If none, courts may infer that the "relevant administrative agency possesses a degree of leeway" to proscribe the preemptive effect of its regulation. *Id.*

²⁵⁰ 21 C.F.R. § 808.1(d)(2) (2007) (no preemption of state or local requirements that are "equal to, or substantially identical to, requirements" imposed under the MDA); *id.* § 808.1(d)(1) (no preemption of "state or local requirements of general applicability").

scope of preemption.²⁵¹ The Justices disagreed on the extent to which they should rely on an agency's position on preemption, though in earlier cases the Court had noted that agency regulations could be informative on defining the scope of preemption where consistent with statutory language.²⁵² The FDA did not consider common law damages actions to be preempted by its device approval regulations.²⁵³

The majority opinion's interpretation of the scope of the preemption provision was substantially informed by the agency's regulations²⁵⁴ because of the unique role²⁵⁵ given to the FDA by Congress.²⁵⁶ After comparing the state common law requirements to the entirely generic concerns of the federal regulations, the majority concluded that the general common law obligations were no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force.²⁵⁷ The majority recognized, however, that where the federal government had weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers, an entirely different case exists for preemption under the statute and its implementing regulations.²⁵⁸

Justice Breyer concurred, agreeing that the relevant administrative agency possessed a degree of leeway to determine which rules, regulations, or other administrative actions will have preemptive effect.²⁵⁹ In particular, the FDA had a special understanding of the likely impact of

²⁵¹ 518 U.S. at 495–96 (“The FDA regulations interpreting the scope of § 360k’s preemptive effect support the Lohrs’ view, and our interpretation of the preemption statute is substantially informed by those regulations.”); *id.* at 505–06 (Breyer, J., concurring); *id.* at 511–12 (O’Connor, J., dissenting).

²⁵² See *CSX Transp.*, 507 U.S. at 670 (involving preemption of common law damages actions under the Federal Railroad Safety Act); *Norfolk & S. Ry. Co. v. Shanklin*, 529 U.S. 344, 355–56 (2000) (involving same and holding agency position on preemption not persuasive when inconsistent with prior agency position and with statutory scheme).

²⁵³ Porter, *supra* note 32, at 7–8.

²⁵⁴ *Medtronic*, 518 U.S. at 495.

²⁵⁵ *Id.* at 496.

²⁵⁶ *Id.* The Court also noted that the FDA is uniquely qualified to determine whether a particular form of state law “stands as an obstacle” to the fulfillment of federal objectives. *Id.* (quoting *Hines*, 312 U.S. at 67).

²⁵⁷ *Id.* at 501–02.

²⁵⁸ *Id.* at 501.

²⁵⁹ *Medtronic*, 518 U.S. at 505–06 (Breyer, J., concurring) (citing *Hillsborough County*, 471 U.S. at 721).

both state and federal requirements, and also an understanding of whether, or the extent to which, state requirements may interfere with federal objectives, and the agency could translate these understandings into particularized preemptive intentions accompanying its various rules and regulations.²⁶⁰ Justice Breyer concluded that the express preemption provision did not fully answer the preemption question.²⁶¹ He therefore applied implied preemption principles, in conjunction with the FDA's own regulatory understanding of preemption, to conclude that there was no actual conflict between the federal requirements and the liability-creating premises of state tort law.²⁶² Justice Breyer had an opportunity to employ those conflict preemption principles for the majority in the Court's next case on preemption of common law damages actions.²⁶³

D. *Implied Conflict Preemption and the FDCA: Geier and Buckman Co.*

In *Geier v. American Honda Motor Co.*, a 2000 Supreme Court case, Justice Breyer endorsed an implied conflict preemption analysis despite the presence of an express preemption provision and a savings clause.²⁶⁴ *Geier* involved allegations that a 1987 Honda was defective in design because it did not have a driver's side air bag.²⁶⁵ The National Traffic and Motor Vehicle Safety Act authorized the Department of Transportation to promulgate Federal Motor Vehicle Safety Standards ("FMVSS").²⁶⁶ The Act's preemption provision states that whenever an FMVSS is in effect, states may not establish or maintain any safety standard applicable to the same aspect of performance that is not identical to the federal standard.²⁶⁷ The "savings clause" stated: "Compliance with any Federal

²⁶⁰ *Id.* at 506.

²⁶¹ *Id.* at 505.

²⁶² *Id.* at 508. Justice O'Connor rejected the FDA's interpretation of the preemption provision insofar as it purported to narrow the plain meaning of the statutory provision. *Id.* at 509, 512 (O'Connor, J., dissenting in part) ("It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference, but one pertaining to the clear statute at issue here is surely not.") (citation omitted).

²⁶³ See *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 864 (2000).

²⁶⁴ *Id.* at 869.

²⁶⁵ *Id.* at 865.

²⁶⁶ National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. §§ 1381-1431 (1966) (current version at 49 U.S.C.A. §§ 30101-30169 (West 1997 & Supp. 2007)). An FMVSS is statutorily defined as a "minimum standard for motor vehicle or motor vehicle equipment performance." *Id.* § 1391(2) (current version at 49 U.S.C.A. § 30102 (West 1997)).

²⁶⁷ *Id.* § 1392(d) (current version at 49 U.S.C. § 30103(b)(1) (2000)).

motor vehicle safety standard issued under this sub-chapter does not exempt any person from any liability under common law."²⁶⁸

The Department of Transportation issued FMVSS 208 regarding Occupant Crash Protection in 1967.²⁶⁹ After several revisions, the 1984 version, at issue in *Geier*, permitted manufacturers to choose, with some restrictions, between air bags and seat belt systems.²⁷⁰ The plaintiff's 1987 Honda did not have a driver's side air bag.²⁷¹ She was injured as a result and sued the manufacturer based on the vehicle's defective design.²⁷²

Justice Breyer, writing for the majority, mirrored his analysis from *Medtronic*, concluding that the express preemption provision did not preempt the plaintiff's common law actions because that provision, read together with the savings clause, did not disclose congressional intent to defeat product liability claims in the face of only a federal minimum standard of safety.²⁷³ The Court then concluded that implied conflict preemption principles continued to operate to the extent that they prohibited *actual conflict*,²⁷⁴ reasoning that it would be impermissible to "take from those who would enforce a federal law the very ability to achieve the law's congressionally mandated objectives that the Constitution, through the operation of ordinary preemption principles, seeks to protect."²⁷⁵

²⁶⁸ *Id.* § 1397(k) (repealed 1994).

²⁶⁹ See *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 34–38 (1983) (history of Standard 208); *Pub. Citizen v. Steed*, 851 F.2d 444, 445 (D.C. Cir. 1988) ("Passive restraint regulation (Standard 208) has advanced over the years along a protracted, winding, sometimes perilous course.").

²⁷⁰ 529 U.S. at 865; see 49 C.F.R. § 571.208 (2007); 49 Fed. Reg. 28,962, 28,999 (July 17, 1984) (Standard 208). For a full discussion of the administrative history of FMVSS 208, see *Geier*, 529 U.S. at 875–77; *id.* at 889–92 (Stevens, J., dissenting). See generally Ralph Nader & Joseph A. Page, *Automobile-Design Liability and Compliance with Federal Standards*, 64 GEO. WASH. L. REV. 415 (1996).

²⁷¹ *Geier*, 529 U.S. at 865.

²⁷² *Id.*

²⁷³ *Id.* at 868.

²⁷⁴ *Id.* at 869.

²⁷⁵ *Id.* at 872. The Court had shown concern for "careful regulatory scheme[s] established by federal law" in its prior implied conflict preemption cases and concluded that the regulatory scheme in *Geier* deserved such concern. *Id.* at 870 (quoting *United States v. Locke*, 529 U.S. 89, 106–07 (2000)). The Court's failure to rely on the express preemption provision has been widely criticized, given its prior reliance on such provisions in both *Cipollone* and *Medtronic*. See Davis, *supra* note 15, at 1005–13; see also Richard C. Ausness, *Preemption of State Tort Law by Federal Safety Statutes: Supreme Court Preemption Jurisprudence Since Cipollone*, 92 Ky. L.J. 913, 967–68 (2003).

The Court found that an actual conflict preempted the plaintiff's action.²⁷⁶ The Court's determination of actual conflict in *Geier* is important to the prescription drug labeling cases in two important respects. First, the Court rejected as conclusive the statutory definition of federal standards as minimum standards of care.²⁷⁷ Instead, the Court reviewed carefully the history of the regulation that had been, at one time or another, unpopular with almost everyone.²⁷⁸ The views of the various Secretaries of Transportation on the objectives of the standard were very influential.²⁷⁹ Similarly, the comments to the original standard and the current Secretary's position, described in an amicus brief in the case, "[that] the 1984 version of FMVSS 208 'embodies the Secretary's policy judgment that safety would best be promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car,'"²⁸⁰ were persuasive. The Secretary sought to balance a variety of concerns that impacted the primary objective of consumer safety, including obstacles to consumer acceptance of restraint devices, industry reluctance to adopt restraint devices, and Congress's responses to public pressures regarding the restraints.²⁸¹ The Court recognized that the standard deliberately sought variety and was, therefore, neither a minimum nor a maximum standard.²⁸²

Second, in defining the federal objectives at issue, the Court placed some weight upon the Department of Transportation's own interpretation of those objectives and its conclusion that the tort actions would stand as an obstacle to those objectives.²⁸³ The Court justified that level of attention—it did not use the word "deference"—to the agency's position based on the technical subject matter, the complex and extensive nature of the relevant history and background, and the agency's uniquely qualified position to comprehend the likely impact of state requirements.²⁸⁴

²⁷⁶ *Geier*, 529 U.S. at 881–82.

²⁷⁷ *Id.* at 874. The National Traffic and Motor Vehicle Safety Act defined the term "safety standard" as a "minimum standard" for vehicle performance. 15 U.S.C. § 1391(2) (1966) (repealed 1994).

²⁷⁸ *Geier*, 529 U.S. at 875–77.

²⁷⁹ *See id.* at 877–85.

²⁸⁰ *See id.* at 881 (citing Brief for United States as Amicus Curiae at 25, *Geier*, 529 U.S. 861 (No. 98–1811)).

²⁸¹ *Id.* at 877–79.

²⁸² *Id.* at 878.

²⁸³ *Geier*, 529 U.S. at 883.

²⁸⁴ *Id.*

The Secretary of Transportation's consistent position on preemption was also influential in supporting the Court's position.²⁸⁵ That position had been articulated in two recent cases, through amicus briefs.²⁸⁶ The lack of a formal statement on preemption was, therefore, not determinative.²⁸⁷ Relying on *Hillsborough County*, the Court rejected a requirement of a formal agency statement on preemption to support conflict preemption.²⁸⁸ Although the Court accepted that it should not find preemption too readily in the absence of clear evidence of a conflict, it reasoned that to insist on a specific expression of an agency's intent to preempt, made after notice-and-comment rulemaking, in some cases would be to tolerate conflicts that an agency, and therefore Congress, is most unlikely to have intended.²⁸⁹

The Court weighed the stated federal objectives against the general interest that the states have in promoting the health and welfare of citizens through compensation for injuries suffered from defective products.²⁹⁰ The Court did not mention specifically the presumption against preemption²⁹¹ but was clearly sympathetic to the states' concerns.²⁹² Nevertheless, the Court concluded that the state and federal objectives could not be reconciled because such a state law, by its terms, would have required manufacturers of all similar cars to install air bags rather than other passive restraint systems, thereby presenting an obstacle to the variety and mix of objectives sought by federal regulators.²⁹³ Although the Court acknowledged that Congress intended some nonuniformity in the regulatory system it created, the Court concluded that jury-assessed standards would lead to unpredictability and uncertainty in the standard of due care.²⁹⁴ The Court recognized that tort law may be different and that related considerations, such as the ability to pay damages instead of modifying one's behavior, may be relevant for preemption purposes, but those considerations were not persuasive in this instance.²⁹⁵

²⁸⁵ *Id.*

²⁸⁶ *Id.* (citing *Freightliner Corp.*, 514 U.S. 280; *Wood v. Gen. Motors Corp.*, 865 F.2d 395 (1st Cir. 1988)).

²⁸⁷ *Id.* at 884.

²⁸⁸ *Geier*, 529 U.S. at 884.

²⁸⁹ *Id.* at 884-85.

²⁹⁰ *Id.* at 882-83.

²⁹¹ *Id.* at 894 (Stevens, J., dissenting); see also Davis, *supra* note 15, at 1008.

²⁹² *Geier*, 529 U.S. at 882.

²⁹³ *Id.* at 881.

²⁹⁴ *Id.* at 871.

²⁹⁵ *Id.* at 882.

The Court's next preemption case again involved the Medical Device Amendments of the FDCA.²⁹⁶ In the 2001 case *Buckman Co. v. Plaintiffs Legal Committee*, the Court was called upon to determine whether the MDA preempted the plaintiffs' claim based on the defendant's fraudulent misrepresentations to the FDA to obtain approval of its orthopedic bone screws.²⁹⁷ The Court used implied conflict preemption principles without engaging in an express preemption analysis, stating that the express preemption provision did not cover the matter.²⁹⁸ Because policing fraud on a federal agency was uniquely federal and not traditionally governed by the states, the Court concluded that the presumption against preemption did not operate.²⁹⁹

The Court began by identifying federal objectives: the federal regulatory scheme empowers the FDA to protect itself from and to deter fraud.³⁰⁰ The Court emphasized the need for flexibility in enforcing that regulatory scheme given its other difficult (and often competing) objectives, including generally protecting medical care practitioners from unnecessary interference with the practice of medicine.³⁰¹ The Court did not mention the FDA's position on the preemption issue, central to *Medtronic* and *Geier*, but the concurring opinion noted that the FDA had waffled on the preemptive effect of its regulatory objectives on state fraud-on-the-FDA claims.³⁰²

The Court found that, because the state law claim was based on a federal regulation and not on traditional tort principles, there was no

²⁹⁶ *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001).

²⁹⁷ *Id.*

²⁹⁸ *Id.* at 348 n.2 ("[W]e express no view on whether these claims are subject to express preemption.").

²⁹⁹ *Id.* at 347-48.

³⁰⁰ *Id.* at 348-49.

³⁰¹ *Buckman*, 531 U.S. at 349-50.

³⁰² *Id.* at 354 n.2 (Stevens, J., concurring). Justice Stevens noted:

Though the United States in this case appears to take the position that fraud-on-the-FDA claims conflict with the federal enforcement scheme even when the FDA has publicly concluded that it was defrauded and taken all the necessary steps to remove a device from the market, that has not always been its position. As recently as 1994, the United States took the position that state-law tort suits alleging fraud in FDA applications for medical devices do not conflict with federal law where the FDA has "subsequently concluded" that the device in question never met the appropriate federal requirements and "initiated enforcement actions" against those responsible for fraudulently obtaining its approval.

Id. (citation omitted).

corresponding benefit to the operation of state law.³⁰³ The tort law deterrent effect could increase burdens on the medical device industry, potentially discouraging the request for approval of devices that might have beneficial off-label uses, in contravention of the stated goal of noninterference with medical practice.³⁰⁴ The Court noted, however, that a traditional state tort action, not based on a federal regulation, might survive.³⁰⁵

E. *Final Words on Implied Preemption Doctrine: Sprietsma and Bates*

The Supreme Court's next two preemption opinions, *Sprietsma v. Mercury Marine* in 2002, and *Bates v. Dow Agrosiences LLC* in 2005, provide additional insight into the Court's implied conflict preemption analysis, though both involve express preemption provisions. Both cases address the importance of agency position on preemption and the value of common law damages actions in regulating conduct.³⁰⁶

Sprietsma involved allegations of design defect against manufacturers of recreational boats that did not have propeller guards.³⁰⁷ The Federal Boat Safety Act of 1971³⁰⁸ gave the Secretary of Transportation the authority, delegated to the Coast Guard, to establish a coordinated national boating safety program, including safety standards for boating equipment to establish uniform safety regulations.³⁰⁹ The Coast Guard, after gathering data and holding public hearings over a several-year period, decided for reasons of safety, feasibility, and economics *not* to require such guards.³¹⁰ The boat manufacturer argued

³⁰³ *Id.* at 352–53 (majority opinion) (federal enactment is critical element of claim, contrasting *Silkwood*, 464 U.S. at 241, and *Medtronic*, 518 U.S. at 481).

³⁰⁴ *Id.* at 350.

³⁰⁵ *Id.* at 353 (“In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question.”). *Buckman*, therefore, could be said not to involve a conflict at all between federal and state interests because states do not have an interest in protecting the FDA from fraud claims. *See id.* For a further discussion of this “false conflict” analysis in preemption, see generally Mary J. Davis, *On Preemption, Congressional Intent and Conflict of Laws*, 66 U. Prrt. L. Rev. 181 (2004).

³⁰⁶ *Bates v. Dow Agrosiences LLC*, 544 U.S. 431, 445–46 (2005); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 69–70 (2002).

³⁰⁷ *Sprietsma*, 537 U.S. at 55. The plaintiff's wife had been thrown from a boat and was killed when struck by the propeller blades. *Id.* at 54.

³⁰⁸ 46 U.S.C. §§ 4301–4311 (2000).

³⁰⁹ S. Rep. No. 92–248, at 1333–35 (1971), as reprinted in 1971 U.S.C.C.A.N. 1333.

³¹⁰ *Sprietsma*, 537 U.S. at 59–60. The Coast Guard referred the study to the National Boating Safety Advisory Council, as required under the statute. 46 U.S.C. § 4302(c)(4). The Advisory Council's 1990 recommendation stated that the data did not support the adoption of a regulation requiring propeller guards, but it would continue to monitor the

that the Coast Guard's decision preempted the plaintiff's claim based on lack of a guard.³¹¹

The Court, consistent with *Geier*, found no express preemption and engaged in an implied conflict preemption analysis.³¹² In assessing the strength of the federal and state governmental policies at stake, the Court emphasized that the Coast Guard regulations had preserved state authority pending the adoption of specific federal regulations.³¹³ The Coast Guard had been in favor of permitting state common law claims.³¹⁴ Although the Court noted that a federal agency decision not to regulate might have preemptive force, the Court found no such force in this case because of the more prominent safety objectives motivating the Coast Guard's decision.³¹⁵

The Court's most recent preemption decision made some important, general observations about the delicate balance that must be achieved in determining the scope of preemption.³¹⁶ *Bates* involved whether common law tort actions challenging the labeling of pesticide were preempted under the Federal Insecticide, Fungicide, and Rodenticide Act (the "FIFRA").³¹⁷ The lower courts had found express preemption of all claims based on a statutory provision forbidding states from imposing requirements for labeling in addition to or different from those required under FIFRA.³¹⁸ They reasoned that a jury finding under state law would *induce* the defendant to alter its pesticide labeling, which the Environmental Protection Agency (the "EPA") had approved.³¹⁹ The EPA had taken inconsistent positions on preemption in the previous five years, first in favor of the operation of state tort law³²⁰ and then in favor of preemption.³²¹

issue for additional information on the state of the design art. *Sprietsma*, 537 U.S. at 61 (quoting 1990 letter to the Advisory Council).

³¹¹ *Sprietsma*, 537 U.S. at 55.

³¹² *Id.* at 63–64. Like the National Traffic and Motor Vehicle Safety Act in *Geier*, the Federal Boat Safety Act had both an express preemption provision and a savings clause. *Id.* at 62–63.

³¹³ *Id.* at 64.

³¹⁴ *Id.* at 65–66. The Court emphasized the government's consistent position that the regulation did not have any preemptive effect. *Id.* at 66.

³¹⁵ *Id.* at 69–70. Finally, the general federal interest in uniformity was an insufficient objective, without more, to create a conflict. *Id.* at 70.

³¹⁶ *Bates*, 544 U.S. at 445–46.

³¹⁷ 7 U.S.C. §§ 136–136y (2000); 544 U.S. at 434.

³¹⁸ *Bates*, 544 U.S. at 436.

³¹⁹ *Id.* at 434–36.

³²⁰ *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 366, 374–78 (Cal. 2000).

³²¹ *Bates*, 544 U.S. at 437 n.7.

The Court's discussion of the history of FIFRA regulation reads much like the history of FDCA regulation.³²² For example, the Court noted that prior to 1910, the states provided the primary and possibly the exclusive source of regulatory control over the distribution of poisonous substances.³²³ The history of the FDCA regarding drugs is virtually identical.³²⁴ In addition, the Court noted that FIFRA imposes misbranding liability for labels that are false or misleading in any particular,³²⁵ just as the FDCA does for prescription drugs and devices. The addition to FIFRA, in 1972, of an express preemption provision that governs the continuing role of the states in pesticide regulation is the primary difference between the two statutory schemes.³²⁶ In addition, the EPA does not determine or endorse the efficacy of pesticides it approves for marketing,³²⁷ unlike the FDA's drug approvals, which do review efficacy claims.³²⁸

In an interesting nod to preemption opponents generally, the Court noted that tort litigation against pesticide manufacturers had been taking place for decades, before and after the enactment of FIFRA in 1947, and that it was not until after *Cipollone* in 1992, that a groundswell of preemption arguments based on FIFRA were advanced.³²⁹ The Court concluded that most claims at issue were not preempted but remanded the case for further inquiry regarding the labeling claims.³³⁰

The Court rejected the theory, relied on by the lower courts, that simply because a jury verdict might have the effect of inducing a manufacturer to make a labeling change, the damages action was therefore preempted.³³¹ The Court reasoned that a requirement is a rule of law that must be obeyed, whereas an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.³³² Consequently, state law requirements that are equivalent to or consistent with FIFRA regulations survived.³³³ Parallel state requirements imposed on

³²² *Id.* at 437–38.

³²³ *Id.* at 437.

³²⁴ See *supra* notes 65–89 and accompanying text.

³²⁵ *Bates*, 544 U.S. at 438.

³²⁶ *Id.* at 439.

³²⁷ *Id.* at 440.

³²⁸ See *supra* note 73 and accompanying text.

³²⁹ *Bates*, 544 U.S. at 441.

³³⁰ *Id.* at 452–53.

³³¹ *Id.* at 445–46.

³³² *Id.* at 445. The Court stated, “The inducement test is unquestionably overbroad”

Id.

³³³ *Id.* at 447.

manufacturers will provide an additional incentive to comply with the federal requirements.³³⁴

The Court took a dim view of expansively reading Congress's intent to preempt given the long history of tort litigation against manufacturers of poisonous substances, which adds force to the basic presumption against preemption.³³⁵ The Court reiterated that if Congress had intended to prevent the operation of a long available form of compensation, it surely would have expressed that intent more clearly.³³⁶ Further, private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA, which contemplates that pesticide labels will evolve over time as manufacturers gain more information about their products' performance in diverse settings.³³⁷ Tort suits, the Court reasoned, can act as a catalyst in this effort.³³⁸

F. *Synthesis of Preemption Doctrine*

The Supreme Court's discussion in *Bates* of the benefit of tort suits in warning cases and the value of those tort actions historically in regulating warnings serves as an important bridge to the implied preemption issue under the FDCA.³³⁹ The following implied preemption principles derived from the Court's cases will impact how the Court analyzes the prescription drug labeling cases.

The presumption against preemption maintains vitality particularly in cases involving traditional areas of historic state power.³⁴⁰ The

³³⁴ *Bates*, 544 U.S. at 448–49. The Court rejected the notion that FIFRA contained a “nonambiguous command to preempt,” given that the EPA had just five years earlier advocated against preemption. *Id.* at 449.

³³⁵ *Id.* at 449; *see id.* at 456, 459 (Thomas, J., concurring) (also endorsing a narrow view of cases in which implied preemption is permitted). Justice Thomas noted:

Today's decision thus comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied preemption This reluctance reflects that preemption analysis is not [a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives, . . . but an inquiry into whether the ordinary meanings of state and federal law conflict.

Id. at 459 (citations and internal quotation marks omitted).

³³⁶ *Id.* at 449 (majority opinion).

³³⁷ *Id.* at 451.

³³⁸ *Id.*

³³⁹ For a discussion of the effect of *Bates* on prescription drug labeling preemption, see DAVID G. OWEN, *PRODUCTS LIABILITY LAW* (2d ed. forthcoming 2008).

³⁴⁰ *See supra* notes 335–338 and accompanying text. The presumption against preemption has also been described as an assumption of nonpreemption that is not triggered in

presumption is especially forceful in implied conflict preemption doctrine because a determination of actual conflict is intended to be a substitute for congressional intent, and, because it is a weak substitute, the Court has been careful to require strong, clear evidence of such conflicts. The Court continues to be sensitive to the role that tort actions play in motivating conduct, and in *Geier* it even left open the possibility that tort actions might survive preemption if narrowly drawn.³⁴¹ The Court appeared, after *Cipollone* and *Medtronic*, to be distancing itself from the protections its preemption doctrine had long provided to common law damages actions.³⁴² *Geier* was similarly reluctant to discuss specifically the presumption against preemption.³⁴³ *Sprietsma* and *Bates*, however, discuss favorably the long-standing role of tort litigation in regulating public health and safety and emphasize the concurrent role of the states in that regulation.³⁴⁴ In addition, the Court has reiterated in *Bates* that where compensation remedies are not otherwise available, the courts should be very hesitant to deny protection to those injured by regulated conduct.³⁴⁵

Determining whether an actual conflict exists will involve an assessment of the federal objectives at stake, as identified through the legislation; the regulations promulgated pursuant to it; the history of that regulation; and the agency's views on the scope of the regulatory scheme.³⁴⁶ The consistency of the government agency's position in defining the objectives and their preemptive reach will be instructive. But the Court has never described the consideration it has given to agency position regarding preemption as deferential; indeed, the Court seems to go out of its way not to speak in terms of deference to the agency on preemptive scope.³⁴⁷ The Court considers carefully the factors that support a finding of actual conflict, and agency position on preemption is one such factor. An agency's position on preemptive scope may be persuasive, given its expertise regarding the federal ob-

areas of significant federal presence. *Locke*, 529 U.S. at 108 (involving preemption of state policies regarding Burma; because foreign affairs are exclusively federal preemption was found).

³⁴¹ See *supra* notes 294–295 and accompanying text.

³⁴² See generally *Buckman*, 531 U.S. 341.

³⁴³ 529 U.S. at 868.

³⁴⁴ See *Bates*, 544 U.S. at 449; *Sprietsma*, 537 U.S. at 70.

³⁴⁵ 544 U.S. at 449–50.

³⁴⁶ See *supra* notes 251–256, 283–289, 313–315, 334 and accompanying text (discussing importance of agency position in *Medtronic*, *Geier*, *Sprietsma*, and *Bates*).

³⁴⁷ See *supra* notes 251–256, 283–289 and accompanying text (noting differences of opinion over level of consideration to be given to agency position in *Medtronic* and *Geier*).

jectives at issue, but not as to the legal conclusion to be drawn from them.

Federal regulatory action necessarily involves a balancing of objectives, sometimes conflicting ones, and requires careful tailoring of the available means to implement those objectives. Does the decision to approve a prescription drug label constitute the kind of particularized balance that will defeat longstanding tort actions which treat such labeling decisions as minimum standards of conduct to be evaluated by the liability-creating premises of state tort law?³⁴⁸ Whether state tort claims actually conflict with or complement the federal prescription drug labeling scheme requires close attention to the details of the balance struck by that regulatory scheme.

IV. DEFINING ACTUAL CONFLICT IN PRESCRIPTION DRUG LABELING PREEMPTION

This Part applies the analysis of implied preemption doctrine to the prescription drug labeling context.³⁴⁹ The FDA's arguments in favor of implied conflict preemption are reiterated, and then the Supreme Court's implied conflict preemption doctrine is applied to those arguments.³⁵⁰ Finally, insights gleaned from the Court's broader preemption doctrine aid in supporting the ultimate conclusion that implied conflict preemption of products liability claims is not supported by FDA labeling regulations.³⁵¹

A. *The Arguments for Implied Conflict Preemption*

Manufacturers who support preemption must define an actual, direct, and clear conflict between state law and federal objectives that requires the conclusion that those federal objectives will be frustrated by the concurrent operation of state tort laws.³⁵² The Court continues to require that traditional state regulation of health and safety not be

³⁴⁸ Both *Hillsborough County* and *Geier* emphasized the importance of the particular balance that the federal regulations sought that might support a finding of actual conflict. See *supra* notes 216–220, 280–289 and accompanying text.

³⁴⁹ See *infra* notes 352–457 and accompanying text.

³⁵⁰ See *infra* notes 352–440 and accompanying text.

³⁵¹ See *infra* notes 441–457 and accompanying text.

³⁵² See *Cloverleaf Butter Co. v. Patterson*, 315 U.S. 148, 156 (1942); *Savage v. Jones*, 225 U.S. 501, 533, 537 (1912).

preempted absent strong evidence of an actual, direct, and clear conflict impairing the accomplishment of defined federal objectives.³⁵³

General federal objectives to promote health and safety do not suffice to conflict with state tort laws and support implied preemption because of the assumption that state laws must be permitted to operate in traditional areas of public health and safety. An actual conflict that impliedly preempts must be based on particularized federal goals that state-mandated actions directly frustrate. The Court's early implied preemption cases involving the FDA make this point³⁵⁴ as do all the modern implied preemption cases.³⁵⁵ Indeed, the FDA has acknowledged that its labeling regulations do not, as a general proposition, preempt all failure-to-warn claims based on approved labeling³⁵⁶ and that "preemptive conflict does not exist in every instance in which state tort law seeks to impose liability for the failure to provide a warning not affirmatively mandated by FDA."³⁵⁷ The FDA has articulated three concerns that its labeling regulations seek to address within the primary goal of ensuring that safe and effective drugs are made available to the public; the following Sections explore these concerns.³⁵⁸

1. Defining Federal Objectives: Over-Warning

First, the FDA asserts that permitting jury verdicts based on approved labeling will encourage manufacturers to warn physicians of unsubstantiated risks and thereby negatively impact medical treatment by inducing physicians to make inappropriate medical treatment decisions.³⁵⁹ This potential over-warning of risks may thus deter the use of an otherwise beneficial drug in circumstances when it is advised.

³⁵³ See *supra* notes 215–223, 276–295, 310–315 and accompanying text (discussing evidence required to support finding of actual conflict); see also Kefauver-Harris Amendments to FDCA, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962) (codified at 21 U.S.C.A. § 321 (West 1999 & Supp. 2007)) (incorporating requirement that "direct and positive conflict" between amendments and state law be established to support preemption).

³⁵⁴ See *supra* notes 151–181 and accompanying text.

³⁵⁵ See *supra* notes 215–223, 276–295, 310–315 and accompanying text.

³⁵⁶ Amicus Curiae Letter Brief of FDA to Judge Stewart Dalzell at 11, *Perry v. Novartis Pharm. Corp.*, 456 F. Supp. 2d 678 (No. CIV 05-5350) (E.D. Pa. Sept. 21, 2006).

³⁵⁷ *Id.*

³⁵⁸ See *infra* notes 359–377 and accompanying text.

³⁵⁹ See *supra* notes 140–141 and accompanying text; see also Brief of United States as Amicus Curiae Supporting Defendant at 16, *Colacicco v. Apotex, Inc.*, No. 06-3107 (3d Cir. June 23, 2006) [hereinafter *Colacicco* Amicus Brief of United States] In an amicus brief, the United States argued:

Under-use of a drug based on dissemination of unsubstantiated warnings may deprive patients of efficacious, possibly live-saving treatment Rather than

The experience with antidepressants documented by the U.S. District Court for the Central District of California in the 2000 case *Motus v. Pfizer, Inc.* illustrates these concerns.³⁶⁰ The FDA studied the alleged association between SSRI antidepressants and the risk of suicide on a number of separate occasions, both before and during the approval process for Zoloft.³⁶¹ Although the FDA never prohibited SSRI manufacturers from altering the labeling,³⁶² it is clear that FDA regularly and consistently from 1991 to 2006 denied that labeling revisions were warranted to enhance the available information about the risk of suicidality from the use of SSRIs.³⁶³ The FDA has consistently argued since 2002 in favor of conflict preemption regarding the labeling of SSRIs because it specifically determined that additional warning of the risk of suicidality was not required by the available evidence.³⁶⁴ Whether such a decision actually conflicts with a common law damages action asserting a need for the warning requires assessment of the remaining asserted federal objectives and their state counterparts.

2. Minimum or Maximum Standards

Second, even though the FDA has long articulated that its regulations establish only minimum standards, the FDA now asserts that in some cases its individual labeling decisions establish more.³⁶⁵ The FDA considers certain labeling approvals to define optimal standards from which deviation is not permitted absent specific FDA ap-

set minimum standards for warnings in drug labeling, FDA seeks to encourage the optimal level of use in light of reasonable safety concerns, by requiring scientific evidence of an association between a drug and a particular hazard before warning of that association on a drug's labeling.

Colacicco Amicus Brief of United States, *supra*, at 16.

³⁶⁰ 127 F. Supp. 2d 1085, 1088 (C.D. Cal. 2000), *rev'd on other grounds*, 358 F.3d 659 (9th Cir. 2004).

³⁶¹ *Id.* at 1089–90. Zoloft, first approved in 1991, was subsequently approved for four additional medical conditions. *Id.* at 1089. During each subsequent approval process, the FDA determined that a stronger warning of the causal connection between use of SSRIs and suicide was not necessary. *Id.* at 1089–90. Of course, the FDA subsequently required a stronger warning of the association between SSRIs and risk of suicide, in a “black box warning” to emphasize the risk. *See supra* note 46 and accompanying text.

³⁶² *Motus*, 127 F. Supp. 2d at 1093–94.

³⁶³ *See Colacicco* Amicus Brief of United States, *supra* note 359, at 8–12; *see also* Nagareda, *supra* note 21, at 25–28 (discussing SSRI regulatory action as “preemption by statement rejection”).

³⁶⁴ *Motus* Amicus Brief of United States, *supra* note 37, at 17–18.

³⁶⁵ *See supra* note 32 and accompanying text.

proval.³⁶⁶ This is the case with SSRI warnings. When a federal regulatory agency describes its standard as more than a minimum, as was the case in the 2002 Supreme Court case *Geier v. American Honda Motor Co.*, a finding of actual conflict is more likely because the particular federal balance may reflect a compromise with the very interests that state tort law serves.³⁶⁷ In 1996, in *Medtronic, Inc. v. Lohr*, the Court viewed the question as a determination of whether the action was one in which the federal government had weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.³⁶⁸ If this is the case, one must ask the next question: what considerations did the federal regulatory scheme balance, and does state tort law directly conflict with that balance? Implied conflict preemption principles require courts to go beyond easy characterizations to assess the actual regulatory action at issue before preempting traditionally complementary state tort actions.

3. Potential Misbranding Violations and Impossibility of Dual Compliance

The FDA notes a third specific concern that, in some instances, a manufacturer may be subject to a misbranding violation if it satisfies a state common law damages action and alters a label that subsequently does not meet with FDA approval.³⁶⁹ In the case of SSRIs, for example, the FDA has expressed the opinion that a manufacturer would be subject to a misbranding violation if it altered its label to comply with a state tort action.³⁷⁰ Such a position implies that requiring a manufacturer to comply with a common law tort action's determination of adequacy would render it subject to federal misbranding liability and thus, make it impossible to satisfy both obligations.³⁷¹

³⁶⁶ See *supra* notes 137–146 and accompanying text.

³⁶⁷ 529 U.S. 861, 877–81 (2002).

³⁶⁸ See 518 U.S. 470, 501 (1996); *supra* notes 257–258 and accompanying text.

³⁶⁹ See *Motus Amicus Brief for United States*, *supra* note 37, at 17. The FDA posited that even though manufacturers are permitted to alter warnings before FDA approval, the FDA must ultimately approve an altered label, which, if found to be misleading, would not be approved. *Id.* The brief stated, somewhat self-servingly, that the FDA would not have approved an altered Zolofit label. *Id.*

³⁷⁰ See *Colacicco Amicus Brief for United States*, *supra* note 359, at 19.

³⁷¹ See *id.*

The Court has rarely found conflict preemption based on impossibility because it has always considered it possible for the defendant to comply with both state and federal regulations, for example by paying tort damages and continuing to comply with a federal requirement.³⁷² In addition, the FDA must establish misbranding liability in court.³⁷³ Misbranding liability does not attach automatically upon mere FDA assertion.³⁷⁴ Whether the Supreme Court would find that it is, indeed, impossible to pay tort damages and simultaneously seek FDA regulatory approval of a stronger warning or provide information to medical care providers through other means, given that the regulations permit this very course, is unlikely.³⁷⁵

Each of these concerns—over-warning resulting in under-utilization of an effective drug and dilution of its otherwise valid warnings, recognition of maximum standard-setting, and the potential misbranding violations that may result from complying with state tort law—are the federal objectives that purportedly require conflict preemption of concurrent state tort laws.³⁷⁶ The next Section analyzes how these objectives are assessed under conflict preemption doctrine when compared to the state tort principles with which they are alleged to conflict.³⁷⁷

B. *Application of Implied Conflict Preemption*

Based on general implied preemption principles and those applicable to the FDCA, prescription drug labeling preemption raises several unresolved questions. First, how are the federal objectives to be defined in the case of prescription drug labeling with which state tort laws arguable conflict? This inquiry requires a careful assessment of the agency's position over time with sensitivity to the history of those objectives. The debate over whether FDA regulations set mini-

³⁷² For an example of impossibility, see *McDermott v. Wisconsin*, 228 U.S. 115, 133–34 (1913), and, see also *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963) (discussing implied preemption involving impossibility).

³⁷³ See *supra* note 50 and accompanying text.

³⁷⁴ See *supra* note 50 and accompanying text.

³⁷⁵ A number of courts have rejected the impossibility component of the implied preemption argument. See, e.g., *Weiss v. Fujisawa Pharm. Co.*, 464 F. Supp. 2d 666, 673–76 (E.D. Ky. 2006); *Perry*, 456 F. Supp. 2d at 684–85; *Levine v. Wyeth*, No. 2004-384, 2006 WL 3041078, ¶¶ 21–23 (Vt. Oct. 27, 2006).

³⁷⁶ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–35 (Jan. 24, 2006); see also Nagareda, *supra* note 21, at 31–32 (rejecting misbranding concern).

³⁷⁷ See *infra* notes 378–440 and accompanying text.

mum or maximum standards is central to defining the objectives in conflict. Second, what effect does the historic presumption against preemption of state regulation in the field of public health and safety have when balanced against those federal objectives? The Court has been hesitant to permit an overly aggressive assessment of federal objectives to swamp the importance of longstanding tort principles.³⁷⁸ Third, does the indirect regulatory effect of common law damages actions create an actual, direct, and clear conflict with the objectives of the prescription drug labeling regulatory regime?

1. Federal Objectives of the Prescription Drug Labeling Regulations

As early as the Supreme Court cases of *Savage v. Jones* and *McDermott v. Wilson*, decided in 1912 and 1913 respectively, the objective of the food and drug laws has been clear: to protect the public health and safety from adulterated and misbranded drugs.³⁷⁹ The FDA, as the undisputed expert federal public health agency charged with ensuring the safety and efficacy of the nation's drug supply, must be given room to satisfy its public health mission substantially unimpeded.³⁸⁰ The federal objectives of public safety, however, are not inconsistent with the historic primacy of the states in the field of public health and safety. Because Congress has not expressed its intent to preempt state regulation, even though it has done so regarding food and drug laws on other occasions,³⁸¹ the states continue to be free to fulfill their historic regulatory role.³⁸²

Implied conflict preemption doctrine substitutes for explicit congressional intent the assessment of actual conflict because Congress is presumed to want its federal objectives to prevail over contrary state law.³⁸³ Because congressional intent is implied based on a particular set of circumstances, the fact that Congress has not defined a specific preemptive scope supports defining those federal objectives with cau-

³⁷⁸ See *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005).

³⁷⁹ See *McDermott*, 228 U.S. at 128; *Savage*, 225 U.S. at 529; *supra* notes 151–170 and accompanying text.

³⁸⁰ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934.

³⁸¹ See Medical Device Amendments to the FDCA, 21 U.S.C.A. § 360k (West 1999 & Supp. 2007); see also *supra* notes 17–18, 129–131 and accompanying text.

³⁸² *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715, 718 (1985); see also *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1035–36 (S.D. Ill. 2001) (discussing FDA preemption position history).

³⁸³ See *Hillsborough County*, 471 U.S. at 713.

tion and particularity so as not to displace state law unnecessarily.³⁸⁴ The Court, therefore, has been restrictive in its definition of what constitutes an actual, direct, and clear conflict with federal objectives.³⁸⁵ Those seeking to preempt state health and safety regulations consequently face an uphill battle.³⁸⁶

The long history of tort litigation³⁸⁷ in the prescription drug labeling area, in addition to the oft-repeated view that Congress would not defeat the operation of a long available form of compensation without making its intent to do so clear,³⁸⁸ also support the requirement of clear, particularized federal objectives to which implied conflict preemption principles are to be applied in the prescription drug labeling context.³⁸⁹ Strong evidence is needed to defeat the presumption that state health laws are not impliedly preempted.³⁹⁰

The FDA has asserted that, given its objective to ensure each drug's optimal use through requiring scientifically substantiated warnings, a common law tort action would frustrate this purpose.³⁹¹ The FDA expressed concern for the potential under-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, which might deprive patients of beneficial, possibly lifesaving treatment.³⁹² According to the FDA, a common law tort action might encourage the use of a warning that would diminish the impact of valid warnings, creating an unnecessary distraction.³⁹³

The FDA's stated objective to prevent over-warning is the kind of general objective that, standing alone, is unpersuasive under this standard.³⁹⁴ Manufacturers often raise over-warning concerns in warning cases because of the fear that juries too easily impose liability based on the hindsight that a particular warning would have prevented the plaintiff's injury, putting manufacturers in the position of having to warn about everything. There is no support, however, for the assertion that

³⁸⁴ See *id.* at 720–21 (defining federal goal narrowly in actual conflict preemption).

³⁸⁵ See *supra* notes 214–223, 276–289 and accompanying text (discussing actual conflict as assessed in *Hillsborough County*, and *Geier*).

³⁸⁶ *Hillsborough County*, 471 U.S. at 714.

³⁸⁷ See *Bates*, 544 U.S. at 449.

³⁸⁸ See *id.* at 450; see also *supra* notes 329–338 and accompanying text.

³⁸⁹ See, e.g., *Witzak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 728–29 (D. Minn. 2005); *Caraker*, 172 F. Supp. 2d at 1031–39.

³⁹⁰ *Hillsborough County*, 471 U.S. at 721.

³⁹¹ See *Motus Amicus Brief of United States*, *supra* note 37, at 23; see also *Colacicco Amicus Brief of United States*, *supra* note 359, at 13.

³⁹² *Motus Amicus Brief of United States*, *supra* note 37, at 23.

³⁹³ *Id.* at 23–24.

³⁹⁴ See *id.* at 23.

this phenomenon occurs in the prescription drug labeling context. Prescription drug labeling is directed at a very sophisticated physician audience. Any over-warning concern must be assessed given the learned intermediary audience, and it is a concern that the FDA substantiates only with very general statements and no supporting data.³⁹⁵ When commenting on the new labeling regulation, physicians uniformly responded that they wanted more, clearer information, not less.³⁹⁶

Even if one acknowledges a general over-warning concern, the FDA has recognized that approved labeling should not by itself preempt state damages actions based on that labeling.³⁹⁷ It would otherwise be difficult to reconcile the FDA's objective to prevent over-warning—that it is beneficial to have less information about a drug's possible risks rather than more—with its own regulation that requires manufacturers to alter a label unilaterally to add or strengthen a contraindication, warning, precaution, or adverse reaction.³⁹⁸ A physician who might be inclined to withhold a particular drug treatment because of disclosed risks may do so for an infinite variety of reasons related to an individual patient's medical needs, only one of which may be sensitivity to over-warning. A more specific regulatory action related to a particular label should be required as an initial matter before any over-warning concern can rise to the level necessary to prevent the concurrent operation of state tort laws which seek to enhance available risk information, not restrict it.

2. Historic State Regulation and the Presumption Against Preemption

The traditional role of the states in regulating food and drug safety, coupled with the historic recognition of the value of common law damages actions in that effort, weighs heavily in the determination of whether state law directly and actually conflicts with federal objectives in the field. As early as *Savage* and as recently as *Bates v. Dow Agrosciences LLC*, decided in 2005, the Supreme Court has acknowledged the importance of state law, including state tort litigation, in providing a remedial component of the regulatory scheme as well as serving as a catalyst in aid of the federal regulatory effort.³⁹⁹

³⁹⁵ See *id.* at 23–24.

³⁹⁶ See *supra* notes 120–121 and accompanying text.

³⁹⁷ See *supra* notes 144–145 and accompanying text (discussing FDA position asserted in amicus letter brief in *Perry*).

³⁹⁸ See *supra* notes 121–124 and accompanying text (discussing 21 C.F.R. § 314.70(c) (6) (2007)).

³⁹⁹ See *Bates*, 544 U.S. at 443; *Savage*, 225 U.S. at 539.

The Court struggled in recent years with the relevance of the presumption against preemption of state police powers in express preemption analysis, but certainly returned to an emphasis on that presumption in 2002, in *Sprietsma v. Mercury Marine* and more recently in *Bates*.⁴⁰⁰ *A fortiori*, the presumption against preemption in the implied preemption context is critical to prevent over-reaching of the traditional state domain. The Court's opinions generally reflect this understanding.⁴⁰¹

For example, in 1985, in *Hillsborough County v. Automated Medical Laboratories, Inc.*, the Court considered the presumption against preemption to apply strongly and defeat implied field preemption.⁴⁰² Regarding conflict preemption, the Court found no evidence of an actual conflict because the stated federal objectives were too speculative to be credited.⁴⁰³

The Court did not mention the presumption by name in *Geier*, though it was keenly aware of the value of state tort law in regulating product safety and, more importantly, providing compensation for injured parties.⁴⁰⁴ The Court was influenced in *Geier* by the particularized nature of the federal objectives—the specific variety and mix of passive restraint systems permitted a choice of design alternatives to achieve a purposeful balance of restraint systems that would be defeated by permitting state tort actions to require only one of those choices.⁴⁰⁵ Permitting a choice of designs to achieve a deliberate balance in the automobile fleet over time was a conscious attempt to delay the accomplishment of maximum safety to enhance other goals of consumer confidence and acceptance.

The objective's behind the FDA's particular labeling approvals simply do not have the same character that supported the variety and mix of objectives that were present in *Geier*. If specific prescription drug labeling approvals support preemption, drug manufacturers would receive, in essence, a free pass to avoid making the otherwise

⁴⁰⁰ See *Bates*, 544 U.S. at 448–50; *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63–66 (2002); *supra* notes 307–315, 334–336 and accompanying text.

⁴⁰¹ See *Geier*, 529 U.S. at 882; *Hillsborough County*, 471 U.S. at 716–21; *supra* notes 207, 214–223, 291–292 and accompanying text.

⁴⁰² See 471 U.S. at 716–21; *supra* notes 207, 214–223 and accompanying text.

⁴⁰³ See *Hillsborough County*, 471 U.S. at 720; *supra* notes 207, 214–223 and accompanying text.

⁴⁰⁴ See *Geier*, 529 U.S. at 882; *supra* notes 291–295 and accompanying text.

⁴⁰⁵ *Geier* represents a strained assessment of actual conflict with which this author and others disagree. See Davis, *supra* note 305, at 231–32; Susan Raeker-Jordan, *A Study in Judicial Sleight of Hand: Did Geier v. American Honda Motor Co. Eradicate the Presumption Against Preemption?*, 17 BYU J. PUB. L. 1, 2–3 (2002).

statutorily required label changes with no simultaneous, conscious purpose to enhance safety or availability. Drug manufacturers who have, or could obtain information about increased risk that would otherwise have to be disclosed will be protected from a failure to disclose. What incentive will then exist to explore postapproval risks and obtain otherwise potentially adverse information? To justify the absolute protection from liability for withholding risk information from sophisticated physicians that preemption would provide on the chance that physicians *may* under-prescribe a dangerous drug requires much stronger support than the generalized concern of over-warning currently articulated.

It is clear that in assessing whether an actual conflict exists the Court openly considers the importance of traditional state regulation in the particular subject area as a strong counterweight to the stated federal objectives in the balance.⁴⁰⁶ If, as the FDA has asserted, its decision not to require a labeling change, as in the case of SSRIs, reflects such a particularized balancing of risks, does its decision not to regulate then become preemptive? *Geier* held that it did; though *Geier* involved an explicit choice to reject a design alternative that was unambiguously safer to accommodate other objectives such as consumer acceptance and reliance.⁴⁰⁷ In *Sprietsma*, the Court rejected a finding of implied conflict preemption in such a circumstance—when a federal agency had decided *not* to regulate—precisely because the agency's conclusion was not an affirmative choice as in *Geier*, but a decision not to choose.⁴⁰⁸ In such a circumstance, the Court was right to conclude that federal objectives did not defeat state tort actions, and rather rely on them as the traditional means of increasing, incrementally, incentives toward safety.⁴⁰⁹ The Court refused to permit an expert agency assessment to have greater effect than necessary.⁴¹⁰

Arguably, an FDA decision *not* to require a particular warning in prescription drug labeling is more like the decision in *Sprietsma* than it is the decision in *Geier*.⁴¹¹ The FDA decisions not to require a particular labeling change in SSRI labels did not prohibit manufacturers from following the labeling change regulations; rather, it reflected the conclusion that at each time, the citizen petitioners had not made a

⁴⁰⁶ See *supra* notes 226, 243, 290–292 and accompanying text.

⁴⁰⁷ 529 U.S. at 886.

⁴⁰⁸ *Sprietsma*, 537 U.S. at 67; *Geier*, 529 U.S. at 877–78.

⁴⁰⁹ See *supra* notes 314–315 and accompanying text.

⁴¹⁰ *Sprietsma*, 537 U.S. at 67–68.

⁴¹¹ *Contra* Nagareda, *supra* note 21, at 30 (likening FDA decision in SSRI case to *Geier*).

compelling case. At no time did any manufacturer seek permission to alter a label; each FDA decision not to require a label change to SSRIs was supported by manufacturers who, one might rationally conclude, had an incentive to prevent the addition of more stringent warnings. Such an FDA decision is more like a decision simply to permit the regulatory scheme to continue operating and to require manufacturers to continue complying with it by seeking necessary labeling changes consistent with those requirements.

And in any event, does the parallel operation of state tort laws actually conflict with the objectives behind such a labeling decision? The Court was openly hostile toward the proposed rejection of "long-standing" principles of tort compensation in *Bates* involving pesticide labeling under FIFRA.⁴¹² The Court confirmed its dedication to the presumption against preemption in assessing Congress's intent and noted that "[p]rivate remedies . . . would seem to aid, rather than hinder," the functioning of a public health and safety regulatory scheme.⁴¹³ *Bates* involved a labeling approval regime less rigorous than the FDA's but operating under an express preemption provision.⁴¹⁴ The concerns for the operation of traditional state tort principles expressed in *Bates* would seem to apply, *a fortiori*, more persuasively in the case of implied conflict preemption under the FDCA.⁴¹⁵

The stated federal objective behind the prescription drug labeling regulation, to prevent over-warning, does not actually conflict with state common law tort actions.⁴¹⁶ The main general objective, protection of the public health, is certainly not in conflict with state tort actions but operates in a complementary way with them, as it has traditionally. The addition of a remedial scheme based on long-standing state tort litigation "would seem to aid, rather than hinder" the functioning of a regulatory scheme based on warning claims, as the Court found in *Bates*.⁴¹⁷ There is no reason, other than the FDA's changed position on preemption, to now treat common law tort actions differently than in the traditional way.

⁴¹² See *Bates*, 544 U.S. at 447–49; *supra* notes 330–335 and accompanying text.

⁴¹³ *Bates*, 544 U.S. at 451.

⁴¹⁴ *Id.* at 437–42.

⁴¹⁵ See *id.*

⁴¹⁶ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006).

⁴¹⁷ 544 U.S. at 451.

3. Effect of the FDA's Changed Position on Preemption

The FDA argues that because labeling approval is solely within the FDA's authority, state common law tort actions may interfere with the balancing of risks that undergird that approval.⁴¹⁸ The concern of over-warning and the consequent possible disincentive to physicians to prescribe are at the core of this argument, but over-warning concerns are not new. The FDA's approval processes continue to be complex and thorough, but appear no more or less capable of assessing warning adequacy today than in years past. To the extent that manufacturers continue to be in control of the data available to substantiate the need for revised warnings, the regulatory process has not changed. The FDA's regulations still require unilateral change to labeling where necessary to identify an increased or different risk even if a causal association is not established.⁴¹⁹ The only real change in the regulatory process is the revised conclusion of preemption that the FDA and manufacturers seek to draw from labeling decisions.⁴²⁰ The recent "groundswell" of effort to use preemption based on FDA approved labeling is another example of an overly aggressive application of the Court's preemption cases.⁴²¹

The Court's implied conflict preemption doctrine rejects such a change in agency position as insignificant in itself to support preemption.⁴²² The FDA's change in position regarding preemption is too recent and too tied to specific litigation to constitute the kind of formal, long-standing agency position, which has been credited as relevant to assessing conflict preemption. In neither *Buckman Co. v. Plaintiffs' Legal Committee*, decided by the Court in 2001, nor *Bates* was such a change in agency position credited in the preemption analysis.⁴²³ *Bates* involved an express preemption provision, for which greater deference to

⁴¹⁸ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3934.

⁴¹⁹ *Id.* at 3949.

⁴²⁰ *Id.* at 3933–35.

⁴²¹ See *supra* note 329 and accompanying text (noting "groundswell" of preemption arguments under FIFRA after *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), revived express preemption analysis).

⁴²² See, e.g., *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 354 n.2 (2001) (Stevens, J., concurring).

⁴²³ See *id.*; *supra* notes 302, 334 and accompanying text; see also discussion of change in agency position as irrelevant in *CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658 (1993), *supra* note 235.

agency interpretation might have been appropriate; nevertheless, the Court refused to endorse it.⁴²⁴

The Court was "substantially informed" by the FDA's position on preemption in *Medtronic* because Congress had expressly provided authority to the FDA to determine when state regulations would be preempted under the MDA.⁴²⁵ The Court did not acknowledge that it was required to give any level of deference to the FDA's interpretation of its preemption authority; Justice O'Connor, in dissent, noted uncertainty as to whether any deference was required in such circumstances.⁴²⁶ There is no formal preemption provision in the new prescription drug labeling regulation. There is only commentary in the preamble.⁴²⁷ There has been no comment from the health care community, either physicians or their organizations, or state public health officials, on the FDA's position in favor of preemption. The proposed regulation specifically disclaimed any intent to alter the FDA's formal position on preemption and, rather, asked for comments on the product liability implications of the proposed labeling regulation itself.⁴²⁸ The new preemption position is nothing more than an articulation of the FDA's very recent litigation position—it is not a long-standing, formal policy, and the Court will likely dismiss any description of it as such in an implied conflict preemption analysis.

An agency's interpretation of its own regulations is ordinarily accorded great deference.⁴²⁹ The degree of that deference has been the subject of much discussion in the Court's preemption opinions, including the opinions involving the FDA.⁴³⁰ Generally, though, the degree of deference due to government positions depends on, among

⁴²⁴ See *supra* note 334 and accompanying text.

⁴²⁵ See *supra* notes 250–258 and accompanying text.

⁴²⁶ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 512 (O'Connor, J., dissenting).

⁴²⁷ See *supra* notes 131–133 and accompanying text. See generally Sharkey, *supra* note 4.

⁴²⁸ Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201) ("[T]his proposed rule does not preempt State law.").

⁴²⁹ See generally *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). As to deference accorded FDA determinations, see 1 O'REILLY, *supra* note 65, § 4:12 (2d ed. 2005 & Supp. 2006). For additional discussion of the deference issue, see Mark C. Levy & Gregory J. Wartman, *Amicus Curiae Efforts to Reform Product Liability at the Food and Drug Administration: FDA's Influence on Federal Preemption of Class III Medical Devices and Pharmaceuticals*, 60 FOOD & DRUG L.J. 495, 504–07 (2005); Nagareda, *supra* note 21, at 23–24; Zieve & Wolfman, *supra* note 30, 308.

⁴³⁰ See *supra* notes 215–223, 251–256, 302 and accompanying text (discussing *Hillsborough County, Medtronic*, and *Buckman Co.*).

other things, consistency, formality, and thoroughness.⁴³¹ Briefs are not accorded great policy deference,⁴³² particularly when the agency interprets statutes or regulations in a particular case, at such a time and in such a manner so as to provide a convenient litigating position for a particular action.⁴³³ The FDA's efforts to obtain greater deference in the MDA context have met with limited success precisely because the FDA is interpreting its own regulation on preemption,⁴³⁴ but even the change in FDA position in the MDA context is being met with significant skepticism.⁴³⁵ Similarly, in *Bates*, the EPA changed its position on preemption within a few years, based on its interpretation of an express preemption provision, and the Court found those arguments particularly dubious because the agency reversed a long-standing no-preemption interpretation.⁴³⁶

Although the Court has rejected an absolute requirement of notice-and-comment rulemaking to justify giving some weight to an agency position on preemption, the consistency and thoroughness of the preemption position is critical for it to be persuasive.⁴³⁷ The FDA's historic position in favor of the concurrent operation of traditional state tort claims is a significant barrier to the recognition of its current preemption position as consistent with federal objectives. The Court has been cautious about the effect of changed agency position, particularly for litigation purposes, as support for preemption.⁴³⁸ Conflict preemption requires assessment of actual conflict based on a particular regulatory act, not from a statutory or regulatory preemption provision. An agency's determination of whether an actual conflict exists is not an *ex ante* determination based on policy but, rather, is an *ex post* assessment based on reflection regarding prior circumstances. Only in *Geier*, in which the Court found implied conflict preemption, was

⁴³¹ *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001); *see also Witzak*, 377 F. Supp. 2d at 730 (explaining that *Motus Amicus* Brief of United States not given deference because there is reason to suspect that brief's interpretation does not reflect "fair and considered judgment" of agency on issue).

⁴³² *Witzak*, 377 F. Supp. 2d at 730; *Nat'l Pharm. Alliance v. Henney*, 47 F. Supp. 2d 37, 39–41 (D.D.C. 1999). *See generally* 1 O'REILLY, *supra* note 65, at § 4:12 (2d ed. 2005 & Supp. 2006).

⁴³³ *See* 1 O'REILLY, *supra* note 65, at § 4:12 (2d ed. 2005 & Supp. 2006).

⁴³⁴ *Riegel v. Medtronic*, 451 F.3d 104, 125 (2d Cir. 2006); *Horn v. Thoratec, Inc.*, 376 F.3d 163, 178–79 (3d Cir. 2004).

⁴³⁵ *See Ausness*, *supra* note 30, at 767–69.

⁴³⁶ 544 U.S. at 449.

⁴³⁷ *Geier*, 529 U.S. at 885; *see supra* note 289 and accompanying text.

⁴³⁸ *See, e.g., Bates*, 544 U.S. at 437 n.7; *Buckman*, 531 U.S. at 354 n.2 (Stevens, J., concurring).

agency position persuasive, and that was based on the Secretary of Transportation's unwavering position on the importance of the federal objectives at issue, and not on a position about preemption per se.⁴³⁹ In the railroad safety regulation cases, the agency's change in preemption position was rejected as inconsistent with the statutory scheme and, thus, of no effect in the express preemption analysis.⁴⁴⁰ Although agency position is given some persuasive treatment, in the case of implied conflict preemption of traditional state tort actions, consistency of position regarding the federal objectives at issue is more important than recency of preemption position in assessing actual conflict.

C. Establishing Direct Conflict: The Dynamic Nature of Risk Information and Minimum Standards

In assessing whether an actual, direct, and clear conflict exists to support implied preemption, the proponent of preemption must establish that conflict with particularized evidence of federal objectives, as explained in *Hillsborough County*.⁴⁴¹ The best argument for preemption in the prescription drug labeling context will be based on the FDA's specific consideration, and subsequent rejection of particular labeling proposed by a manufacturer that the FDA finds to be unsubstantiated based on the available data. The Court is unlikely to be persuaded by the speculation and hyperbole that the regulatory sky is falling if a labeling change proposed by tort claimants is permitted, however, and in this context the long-standing characterization of FDA labeling approval decisions as minimum standards will weigh in favor of finding no conflict.

In the prescription drug labeling context, the dynamic nature of the scientific understanding of risk and the way that risk is discovered and appreciated by manufacturers, regulators, and physicians disfavor preemption. In *Bates*, which involved pesticide labeling, the Court refused to give broad scope to the preemption provision at issue because doing so would stifle an otherwise dynamic need to continually evaluate risks about which warnings should be provided.⁴⁴² Inertia is a powerful force: if preemption is available based on a particular labeling approval, what manufacturer would expend effort and resources to identify the need for any further labeling change? The onus would

⁴³⁹ See *supra* notes 279–281 and accompanying text.

⁴⁴⁰ See *supra* note 235 and accompanying text.

⁴⁴¹ See *supra* notes 205–208 and accompanying text.

⁴⁴² See 544 U.S. at 451; *supra* notes 336–337 and accompanying text.

be on the FDA and the public to police the scientific advances regarding each prescription drug approved and then propose and establish the need for labeling changes without the active assistance of the manufacturers, who would have no financial incentive to support a label change. Why would a manufacturer spend any resources on acquiring information about a product's risks when a label already protects it from liability?

This is, in effect, where the process is now because manufacturers rarely propose labeling changes postmarket and, when they do, it is often too little, too late. To place the postmarket obligation exclusively on the FDA and other public groups would destroy the ability of the FDA to regulate effectively the postmarketing risks stemming from the large number of prescription drugs it oversees. One can only imagine the paralysis that would accompany any labeling approval to which preemption attached under such a scheme.

Indeed, many commentators, and also more recently the Government Accountability Office, have criticized the FDA's inability to obtain full information from prescription drug manufacturers because the reporting process for postapproval adverse reaction events and clinical trials is too weak.⁴⁴³ The FDA does not have sufficient authority to require additional clinical trials after drug approval.⁴⁴⁴ Consequently, many have argued that the tort litigation system acts as an important avenue by which the health care community learns of safety and efficacy information.⁴⁴⁵

Professor Richard Nagareda has suggested that one of the preconditions for preemption should turn on the provision of information by manufacturers that is the logical predicate for a regime of optimal regulation.⁴⁴⁶ This proposal is entirely consistent with the current way tort law operates, *sub silentio*, under the presumption against preemption in the balance against purported federal objectives. Unless federal objectives can be articulated in a way that ensures, in the labeling context, that manufacturers have a continuing incentive to enhance a product's safety through acquiring and sharing risk information, actual

⁴⁴³ See *supra* note 77 and accompanying text.

⁴⁴⁴ See GAO REPORT, DRUG SAFETY, *supra* note 77, at 11.

⁴⁴⁵ Joe Pickett, *Pressure Building for FDA to Mandate Post-Approval Studies After Vioxx Incident*, 4 BIORESEARCH MONITORING ALERT, Dec. 1, 2004, at 1 (explaining that FDA cannot mandate post-marketing safety programs; FDA has never been given enough staff to "keep careful track of adverse reactions that are reported for drugs.") (citations omitted); Young, *supra* note 32, at 1.

⁴⁴⁶ Nagareda, *supra* note 21, at 40–41.

conflict is not established. Professor Nagareda soundly envisions that preemption doctrine can maximize the flow of information to enhance regulatory decision making and provide manufacturers with protection against the operation of the tort system.⁴⁴⁷

Professor Richard Epstein asserts, to the contrary, that information about potential risks is available from a wide variety of other sources, so preemption of tort claims will not prevent the availability of adverse risk information.⁴⁴⁸ Professor Epstein proposes a broad sweep for preemption of tort claims under an expanded notion of field preemption, out of a greater concern for enhancing product innovation by streamlining the regulatory processes in general.⁴⁴⁹ The proposal that the entire drug regulatory process needs improvement produces no disagreement and is not inconsistent with permitting tort claims as an oversight mechanism regarding currently approved products and knowledge of their true risks. Such actions ask for assessment of the very information that Professor Epstein suggests is otherwise widely available and that the FDA also seeks: information about risk that may change the very reason the product was approved—to enhance the users' health safely and effectively.⁴⁵⁰ He acknowledges that the reason for allowing products to stay on the market despite their risks is to permit users the opportunity to self-select.⁴⁵¹ Self-selection occurs only with full information, in this instance, to the medical care provider. Availability of full information is not possible while the system intended to encourage that full disclosure provides no effective mechanism to ensure its availability.

One example will illustrate the weakness of the FDA regulatory system that should weigh against preemption. Merck & Co. received approval from the FDA to market its anti-inflammatory drug Vioxx for use in treating arthritis pain in February 1999.⁴⁵² In June 2000, Merck submitted data to the FDA disclosing a four-fold higher risk of heart attacks compared to another pain-reliever, but not until April 2002 did the FDA approve a new warning that referred to an increase in cardio-

⁴⁴⁷ See *id.* at 41.

⁴⁴⁸ Epstein, *supra* note 21, at 30.

⁴⁴⁹ *Id.* at 26, 30–31.

⁴⁵⁰ See *id.* at 30.

⁴⁵¹ See *id.* at 32.

⁴⁵² See *In re Vioxx Prods. Liab. Litig.*, No. MDL 1567, 2007 WL 195296, at *3–4 (E.D. La. July 3, 2007). For a discussion of the circumstances involving Vioxx, see generally Jonathan O'Steen & Van O'Steen, *The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs*, 48 ARIZ. L. REV. 67 (2006).

vascular risks.⁴⁵³ Merck voluntarily recalled Vioxx from the market in September 2004, because results of another clinical trial vindicated the first and indicated a doubled risk of cardiac events in those who used Vioxx.⁴⁵⁴ After Merck withdrew Vioxx from the market Congress held hearings on the FDA's alleged regulatory failure to require stronger warnings sooner.⁴⁵⁵ The FDA spokesman that stated the FDA needed more regulatory authority to require warning labels after safety concerns surface postapproval.⁴⁵⁶ The Vioxx warning label change was delayed for one year while the FDA and Merck negotiated over it.⁴⁵⁷

Although the current practice may be that manufacturers wait for FDA approval before making labeling changes, that practice does not, nor should it, prevent manufacturers from acting on risk information. The statutory scheme imposes on manufacturers a greater obligation to protect the public safety. Tolerating or ignoring a failure to fulfill that obligation is inconsistent with the statutory mandate. The FDA may tolerate, even encourage, the practice of permitting manufacturers to not change labeling until approval is obtained, but permitting common law tort actions to operate concurrently does not conflict with either the statutory or regulatory mandate that requires more. Tort liability might increase the likelihood that manufacturers will seek FDA approval of a labeling change, pursuant to the obligation to add significant risk information unilaterally based on evidence that is only available to it and, perhaps, only likely to be disclosed through the litigation process. In this way, state tort claims advance, rather than conflict with, federal objectives.

CONCLUSION

To permit preemption based on an FDA-approved label, even one that specifically rejected proposed language as unsubstantiated, will create a disincentive to manufacturers to act promptly based on acquired evidence of risk. Indeed, it creates a disincentive to *seek* in the first instance evidence of increased risks or adverse side effects which may be available. Knowledge of adverse side effects and evidence of increased risk come to drug manufacturers in a wide variety

⁴⁵³ O'Steen & O'Steen, *supra* note 452, at 68.

⁴⁵⁴ *Id.* at 67–68.

⁴⁵⁵ See *Ensuring Drug Safety*, *supra* note 76.

⁴⁵⁶ See *id.*

⁴⁵⁷ *In re Vioxx*, 2007 WL 195296, at *4.

of ways.⁴⁵⁸ The FDA approves labels based on information submitted to it by manufacturers,⁴⁵⁹ and it relies on manufacturers to provide the information required under its regulations.⁴⁶⁰ The FDA is not an investigative agency; it is a regulatory agency. It, like other regulatory agencies, receives information from members of the industry it regulates and acts on that information. It does not actively seek out information to accomplish these goals unless information is brought to it highlighting a need to do so. The tort litigation system is one such avenue of information that would be closed if preemption operated under these conditions; it is an avenue that needs to operate concurrently with the regulatory system that does not have authority to require the regulated industry to engage in efforts to obtain or report all adverse risk information.⁴⁶¹

The history of SSRI antidepressant labeling used throughout this Article is instructive.⁴⁶² Citizen petitions were presented to the FDA on three occasions seeking to convince the FDA to require an enhanced label regarding the risk of suicidality.⁴⁶³ The FDA refused to require such a label until 2004, when it issued a public health advisory to that effect.⁴⁶⁴ The FDA asked manufacturers for additional information about studies on other antidepressants and ultimately acknowledged that additional data and analysis were needed, including increased public discussion. This information was slow to materialize and were it not for the actions of nonmanufacturers, it might never have. If preemption had been available, and the common law tort system had not been active to bring some of this information to light, the warning might not yet be provided. Indeed, it is wrong to suggest

⁴⁵⁸ See *Motus Amicus Brief of Public Citizen*, *supra* note 46, at 18–19; see also Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 591 (2005) (preemption removes opportunity for litigation system to aid in effort to monitor product safety).

⁴⁵⁹ 21 C.F.R. § 314.50 (2007) (content for format of an application for new drug approval).

⁴⁶⁰ *Id.* § 314.80 (post-marketing reporting of adverse drug experiences).

⁴⁶¹ See *Ensuring Drug Safety*, *supra* note 76.

⁴⁶² See *supra* notes 358–377 and accompanying text.

⁴⁶³ See *supra* note 46 and accompanying text.

⁴⁶⁴ Public Health Advisory, FDA, Worsening Depression and Suicidality in Patients Being Treated With Antidepressant (Mar. 22, 2004), available at <http://www.fda.gov/cder/drug/antidepressants/AntidepressantPHA.htm> (recommending labeling for antidepressants like Zoloft be modified to reflect potential suicide risks).

that the FDA rejected a stronger warning in the case of SSRIs because the manufacturers never sought it.⁴⁶⁵

The FDA's final argument that its regulations provide optimal, not minimum, standards is inconsistent with the regulatory scheme it administers. The unilateral obligation of manufacturers to alter warnings when substantial risk information comes to them and the FDA's inability to require postmarketing trials to obtain risk information substantially undercut any argument that the labeling regulation was intended to provide a maximum standard of care. In the case of prescription drug labeling, there is unlikely ever to be full information of risk on which to base the conclusion that any labeling should be considered a maximum, or optimal, one, frozen for all time with only the regulated industry with an incentive to shed additional light.

Implied conflict preemption based on approved drug labeling would be an expansive application of the Court's conflict preemption doctrine. The FDA's new position on preemption, applied not retroactively but prospectively, might one day be characterized as a consistent agency position on preemption for those prescription drugs that fall within it. That day is in the distant future. As to currently produced and marketed prescription drugs, the FDA's long-standing and traditional position against preemption will continue to control.

No labeling regulation can create the perfect incentive for manufacturers to seek better and more complete information regarding the adverse side effects of the prescriptions we take. In a world where U.S. patients receive proper medical care only fifty-five percent of the time,⁴⁶⁶ pharmaceutical companies are in control of the research conducted on their products premarketing and postmarketing,⁴⁶⁷ pharmaceutical sales representatives have increasing influence on the drugs that physicians prescribe,⁴⁶⁸ and the pharmaceutical industry is the largest lobbying group in the United States,⁴⁶⁹ the products liabil-

⁴⁶⁵ See generally Brief of Appellants, *Colacicco v. Apotex, Inc.*, No. 06-3107 (3d Cir. June 23, 2006).

⁴⁶⁶ *Proper Health Care Put at 55%*, ASSOC. PRESS, Mar. 16, 2006 (on file with the Boston College Law Review), available at http://www.bc.edu/schools/law/lawreviews/bclawreview/Past_Issues.html (reporting on a study in the *New England Journal of Medicine*).

⁴⁶⁷ PHRMA, PHARMACEUTICAL INDUSTRY PROFILE 2005 at 3 fig.1.2 (2005) (industry funds research at almost twice the level of the National Institutes of Health).

⁴⁶⁸ Carl Elliott, *The Drug Pushers*, ATLANTIC MONTHLY, Apr. 2006, at 82-83 (studies in medical literature indicate that doctors who take gifts from a drug company are more likely to prescribe that company's drugs or ask that they be added to a hospital's formulary).

⁴⁶⁹ *Id.* at 88.

ity litigation system is a critical component to create incentives for greater access to risk information to ensure the public's health. The Supreme Court's implied conflict preemption doctrine as applied to the FDA's prescription drug labeling regulations supports this conclusion and weighs state tort litigation strongly in the battle over implied preemption.